

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products)
Liability Litigation,) MD 15-02641-PHX-DGC
)
_____))
)
Lisa Hyde and Mark Hyde, a married) Phoenix, Arizona
couple,) October 1, 2018
)
Plaintiffs,)
)
v.) CV 16-00893-PHX-DGC
)
C.R. Bard, Inc., a New Jersey)
corporation, and Bard Peripheral)
Vascular, an Arizona corporation,)
)
Defendants.)
_____)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 10 - P.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
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P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Thank you. Please be seated.

Counsel, as the jury was going out, Juror Number 2, who is the older gentleman on the back row with the beard, asked Traci if he could ask questions of the witnesses. And and Traci said if you have any questions, put it in a note to the judge.

So he filled out a note, or wrote a note, that at the top says "Mr. Carr," so I think he's identifying the questions that he wants to ask. The first one is, "When doing animal testing, are the animals penned up or let run free like you would a human?" I did a little editing of the language but that's the question.

The second question is, "You say you have a patent. For what? Is it a medical device?"

Signed Juror Number -- Jury Number 2.

My view is that we shouldn't start the practice now of having the jurors ask questions in the middle of the trial when other witnesses haven't been subject to it, and also when we're on a tight timeline. So my inclination would be to simply tell the jury when they come in, in this court we don't have the jurors ask questions; the lawyers will ask the

12:57:09 1 questions they think are relevant.

2 Do any of you have a different view?

3 MR. ROGERS: I don't, Your Honor. I agree with your
4 conclusion.

12:57:20 5 MR. O'CONNOR: Well, it could help us.

6 MR. LOPEZ: Okay, here's what I'm thinking. My
7 thoughts. We -- certainly those questions shouldn't be asked
8 of the witness, but is it wrong just for the jurors to pose
9 questions to you that you share with us?

12:57:35 10 THE COURT: Well, that's a practice that can be
11 adopted. We use it in our state court here. We haven't
12 adopted it here in federal court. And we can talk about that
13 for the next bellwether trial. But I'm quite uncomfortable
14 adopting it on Day 10 of a trial.

12:57:50 15 It seems to me if we want to do it, we should do it
16 from the start. We should factor that into the time we allow
17 for the trial.

18 But I don't think it's wise to start midstream when
19 all of the witnesses haven't been subjected to questions that
12:58:02 20 the jurors might have.

21 MR. LOPEZ: I agree. Once you say it, then it's
22 going to encourage -- you'll get notes every day.

23 THE COURT: Well, I think that's true. I think
24 that's -- that's a potential down side. You spend time on
12:58:15 25 jury questions.

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

1 But since it's in the middle of the trial, do
2 disagree we should tell this jury we're not going to have the
3 jurors ask questions and leave it at that?

4 MR. LOPEZ: We agree, Your Honor.

12:58:25 5 THE COURT: Okay.

6 All right, we'll bring in the jury.

7 (The jury entered the courtroom at 1:00.)

8 THE COURT: Thank you. Please be seated.

9 Members of the jury, I received from Traci a note
13:00:31 10 that I think was written by Juror Number 2. The basic issue
11 presented by the note is whether jurors are permitted to ask
12 questions to be submitted to witnesses or asked of witnesses.

13 Although that's done in some courts, it's actually
14 done in Arizona state court, it's not very common. It hasn't
13:00:49 15 been adopted in federal court and doesn't happen in this
16 Court. So we won't be asking your questions. We appreciate
17 your interested in the subjects. The lawyers will ask all the
18 questions they believe is relevant for you to consider.

19 All right. You may proceed, Mr. Rogers.

13:01:04 20 MR. ROGERS: Thank you, Your Honor.

21 **SHARI O'QUINN,**

22 recalled as a witness herein, after having been previously
23 sworn or affirmed, was examined and testified as follows:

24

25

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

1 D I R E C T E X A M I N A T I O N (CONTINUED)

2 BY MR. ROGERS:

3 Q Ms. O'Quinn, I think before the break we had talked about
4 some of the work that did you with Dr. Venbrux and reviewing
13:01:17 5 some of the images that related to the EVEREST study.

6 And was there a point where a larger meeting occurred
7 with a group of doctors?

8 A Yes.

9 Q And what brought that meeting about?

13:01:31 10 A That meeting was part of our ongoing investigations. We
11 wanted to get a larger group of physicians together and get
12 input on our current rates of events and perspective.

13 MR. ROGERS: Can we pull up Exhibit 5539, please.

14 Your Honor, may I display? This is in evidence.

13:01:58 15 THE COURT: Let me just confirm that. 5539.

16 THE COURTROOM DEPUTY: Yes.

17 THE COURT: Yes, you may.

18 MR. ROGERS: Can you go to page 8, please.

19 BY MR. ROGERS:

13:02:07 20 Q And is the portion at the bottom here --

21 MR. ROGERS: Can you pull that out, Scott. Thanks.

22 BY MR. ROGERS:

23 Q Is the portion we here -- we see here at 6.4, Physician
24 Panel, is this a description of the meeting you were
13:02:18 25 describing?

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:02:21 1 A Yes, it is.

2 Q And did you attend that meeting yourself?

3 A Yes, I did.

4 Q And do you know who else from Bard was in attendance at
13:02:30 5 that meeting?

6 A Yes. There was a large number of people who attended. It
7 included most of the executives on the leadership team,
8 including our CEO, our director of R&D, director of marketing.
9 A number of different people from Bard who were interested in
13:02:51 10 hearing the physicians' perspective.

11 MR. ROGERS: Can you take that down, Scott, and pull
12 up 5537.

13 BY MR. ROGERS:

14 Q Can you tell us what this document is, please.

13:03:10 15 A I think this is the slide deck, but I would need to see
16 another page.

17 MR. ROGERS: Can we go one more.

18 THE WITNESS: Okay. Yeah. This is this appears to
19 be the slide deck that was presented at that meeting that
13:03:31 20 included the attendees from Bard, the physicians, and the
21 agenda.

22 BY MR. ROGERS:

23 Q And did you provide input into the content of the
24 presentation?

13:03:40 25 A Yes.

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:03:41 1 Q And would this PowerPoint presentation have been
2 maintained at Bard in the ordinary course of business?

3 A Yes.

4 MR. ROGERS: Your Honor, I move this into evidence.

13:03:52 5 MR. O'CONNOR: No objection.

6 THE COURT: Admitted.

7 (Exhibit 5537 admitted.)

8 MR. ROGERS: May we display?

9 THE COURT: Yes.

13:03:58 10 MR. ROGERS: All right. Let's turn, I guess, first
11 to the second page, please.

12 BY MR. ROGERS:

13 Q And does this describe or is this a list of the doctors
14 who attended the meeting?

13:04:09 15 A Yes.

16 MR. ROGERS: If you would, let's go to the following
17 page.

18 BY MR. ROGERS:

19 Q Is that a list of the individuals from Bard who
13:04:17 20 participated in the meeting?

21 A Yes.

22 Q All right.

23 MR. ROGERS: Can we go to page 14, please.

24 BY MR. ROGERS:

13:04:26 25 Q And can you tell us what we're seeing here on the screen.

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:04:29 1 A Yes. This is a summary of the complaint history that had
2 been received to date with the filter and the types of
3 complaints, and this was shared with the physicians.

4 Q And why did you share this information with the
13:04:45 5 physicians?

6 A We wanted to be transparent with them so that they could
7 understand the types of events that had occurred with the
8 product and gain their perspective as part of our ongoing
9 investigation.

13:04:57 10 Q All right.

11 MR. ROGERS: Can we go to page 16, please.

12 BY MR. ROGERS:

13 Q And what are we seeing here?

14 A This is a summary of the events broken down by symptomatic
13:05:15 15 versus asymptomatic, and nine patients were asymptomatic, or
16 75 percent of them were asymptomatic. And then we broke it
17 out by gender as well in order to see if there were any
18 trends.

19 Q And was this information shared with the physician panel?

13:05:33 20 A Yes.

21 MR. ROGERS: All right, we can take that down. And
22 can we return to Exhibit 5539, please.

23 And, Your Honor, may we display?

24 THE COURT: Yes.

13:05:48 25 MR. ROGERS: Would you go to pages 8 and 9, please.

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:05:50 1 BY MR. ROGERS:

2 Q If you look at the bottom of page 8 and top of page 9, is
3 that a summary of the physician panel meeting?

4 A Yes, it is.

13:06:17 5 Q And was that included in the Failure Investigation Report?

6 A Yes.

7 Q And why was that information included in the Failure
8 Investigation Report?

9 A Because that was important feedback that we needed to make
13:06:30 10 sure that we were fully assessing the risks and the benefits
11 and we wanted to have that -- that external unbiased
12 perspective.

13 Q All right.

14 MR. ROGERS: Can you pull out the bottom of page 9
13:06:42 15 where it says "CEC meeting."

16 BY MR. ROGERS:

17 Q And can you tell us what a CEC is?

18 A That's a clinical events committee. And that's a
19 committee, a safety monitoring committee, that we contracted
13:06:59 20 as part of the EVEREST study and it's an independent group
21 that has the medical monitor and they review any of the
22 events, the adverse events that occur and they do that as an
23 independent unbiased group that reviews those events.

24 Q And the top of the box there indicates that there was a
13:07:26 25 meeting on June the 19th, 2006. Do you see that?

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:07:31 1 A Yes.

2 Q And do you personally attend that meeting?

3 A Yes, I did.

4 Q And was -- there's a reference here to also the medical
13:07:38 5 monitor, Dr. Kandarpa. Do you see that?

6 A Yes.

7 Q Was he in attendance at that meeting?

8 A Yes, he was.

9 Q And why did Bard meet with Dr. Kandarpa?

13:07:49 10 A Throughout the clinical study you meet with the medical
11 monitor or the CEC periodically to review the events, and on
12 this particular meeting I personally attended in order to give
13 Dr. Kandarpa an update on our commercial experience with the
14 product and any of the events that had occurred to date.

13:08:09 15 Q What do you mean when you say "commercial experience"?

16 A That means while we were doing the clinical study for the
17 retrievable indication the product was still being sold for a
18 permanent indication. So we had commercial experience with
19 the device.

13:08:23 20 Q And what was Dr. Kandarpa's role in the EVEREST study?

21 A Dr. Kandarpa's role is that of the medical monitor. And
22 his role is to review the safety of the device throughout the
23 clinical study and any safety information that the
24 manufacturer has about the product and make recommendations to
13:08:44 25 the company about whether he has concerns, if the study should

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:08:50 1 be stopped or in any way modified.

2 Q Okay.

3 MR. ROGERS: Can we take that down and pull up
4 Exhibit 5538, please.

13:09:00 5 BY MR. ROGERS:

6 Q Can you identify this document for the record, please.

7 A Yes. This is a summary of the meeting minutes for the
8 medical monitor meeting that I attended that I just
9 referenced.

13:09:19 10 Q And so do you know who would have prepared these minutes?

11 A These minutes are prepared by Dr. Kandarpa and the
12 representatives at BBA, which is the company he worked with.

13 Q And were these -- I'm sorry, I cut you off. Let me let
14 you finish.

13:09:36 15 A They prepared by Dr. Kandarpa and BBA, which is the group
16 that Dr. Kandarpa worked for.

17 MR. ROGERS: Okay. Can we go to the last page,
18 please. I'm sorry, back it back.

19 Let's go back to the front, that might be a more
13:10:01 20 expeditious way to do this.

21 Go to the next page.

22 And then the next page. There you go.

23 BY MR. ROGERS:

24 Q So would Bard receive the minutes from this entity, BPA?

13:10:10 25 A Yes. We would receive the minutes after the meeting.

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:10:15 1 Q And would you see those minutes when they came into Bard?

2 A Yes.

3 Q And is this Dr. Kandarpa's signature, as best you know, on

4 the minutes?

13:10:24 5 A Best as I know, yes.

6 Q And when you received these minutes, would they typically

7 be signed off by Dr. Kandarpa?

8 A Yes, they would be. And sometimes when we would audit our

9 files, if we would see documents that were not signed, our

13:10:39 10 quality control group would follow up and request signed

11 documentation.

12 Q And where did this meeting take place?

13 A This meeting took place in -- just outside of Boston,

14 Massachusetts.

13:10:54 15 Q And were there other employees of Bard that attended this

16 meeting?

17 A Yes. Our clinical study manager was present and also our

18 chief medical officer from Bard was also present.

19 Q And did you travel from the Phoenix area to Boston to

13:11:10 20 attend this meeting?

21 A Yes.

22 Q And why did you decide to go to this meeting in person?

23 A Because I wanted to make sure I personally was able to

24 deliver to Dr. Kandarpa a summary of our events, because the

13:11:24 25 investigation was ongoing and we felt it was really important

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:11:27 1 to be transparent with him and share that information so we
2 could include that in our investigation report.

3 Q And what other topics were -- did you discuss at that
4 meeting?

13:11:40 5 A I would have to look at the slides, but I recall us
6 discussing our commercial experience, also the specific events
7 that had occurred in the EVEREST study that we wanted to make
8 him aware of. And I can't -- I can't recall. But if I saw
9 the meeting minutes, we had detailed meeting minutes from
13:12:03 10 those.

11 Q Understand. Do you recall if the subject of caudal
12 migration as it occurred in the EVEREST study was discussed at
13 this meeting?

14 A Oh, yes. Yes.

13:12:13 15 Q What sort of information was provided by you at this
16 meeting regarding caudal migration?

17 A We provided a summary of all of the events that we were
18 aware of regarding caudal migration from the clinical study
19 and from our commercial experience.

13:12:28 20 Q And at this meeting, would Dr. Kandarpa have had an
21 opportunity to voice any concerns he had about the study?

22 A Yes. That was the purpose of the meeting.

23 Q And would Bard have welcomed the feedback that they would
24 receive from Dr. Kandarpa?

13:12:43 25 A Absolutely. We were -- not only would we have welcomed

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:12:46 1 it, but we would have been obligated to respond to it and also
2 potentially report it to the FDA.

3 Q And would you have expected Dr. Kandarpa as the medical
4 monitor to tell Bard if he believed there were safety issues
13:13:00 5 with the study?

6 A Yes. That was the purpose of his role.

7 MR. ROGERS: Okay, we can take that down. Would you
8 please call up Exhibit 5946, please.

9 BY MR. ROGERS:

13:13:19 10 Q Can you identify this or would you need to see a few more
11 pages?

12 A I need to see a few more pages. I'm generally familiar
13 with what the review board is, but not this specific document.

14 Q Sure. Can you scroll through a couple more pages, please.

13:13:44 15 Okay, can you tell us what this document is?

16 A Yes. The quality management board review is something
17 that's part of our quality system. We would summarize all of
18 our quality information and present it to the executive
19 management team on a regular basis and this is looks like the
13:14:01 20 slides that were presented at the July 2006 meeting.

21 Q When you say slides, do you mean PowerPoint?

22 A PowerPoint. Yeah.

23 Q And would you have had input into the slides that were
24 used at this meeting?

13:14:15 25 A Yes.

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:14:15 1 Q Were you knowledgeable about these slides?

2 A Yes.

3 Q And were these slides kept in the ordinary course of
4 business at Bard?

13:14:24 5 A Yes.

6 MR. ROGERS: Your Honor, I move this into evidence.

7 MR. O'CONNOR: May we scroll through?

8 No objection.

9 THE COURT: Admitted.

09:25:03 10 (Exhibit 5946 admitted.)

11 MR. ROGERS: May we display?

12 THE COURT: You may.

13 BY MR. ROGERS:

14 Q What is the date of this meeting?

13:15:04 15 A July 18, 2006.

16 Q And who would typically attend quality management board
17 review meetings?

18 A It was the entire executive management team from our -- I
19 refer to them as the CEO but he was actually, I believe,
13:15:19 20 president. And our heads of quality, regulatory, me,
21 regulatory and clinical, head of R&D, and the sales and
22 marketing VP as well.

23 MR. ROGERS: Can we go to page 22 of this document.
24 And make that, hopefully, a little bit bigger.

25

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:15:40 1 BY MR. ROGERS:

2 Q Can you read that?

3 A Most of it.

4 Q Okay.

13:15:45 5 MR. ROGERS: Is there a size down or is that --
6 that's it?

7 BY MR. ROGERS:

8 Q I don't know if that helps or not. Can you see that?

9 A I can see most of it. Some of the dates are a little
13:16:00 10 blurry.

11 I can see everything except those call-outs are a
12 little too blurry.

13 Q Can you tell us generally what this is?

14 A Yes. This is a summary by month of the number of
13:16:31 15 complaints that occurred, and then these charts are shaded
16 based upon the type of product so you could see the types of
17 complaints and the number of them that had occurred over that
18 period of time from November '05 to June of '06.

19 Q And was this information discussed at the quality review
13:16:53 20 meeting?

21 A Yes.

22 Q And what action came out of this meeting?

23 A I -- there would be meeting minutes from the meeting that
24 I would have to look at to see specifically what action, but
13:17:09 25 from what I recall it was that we would continue the failure

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

1 investigation and continue monitoring the events.

2 Q Okay. Let's talk --

3 MR. ROGERS: Can you take that down and let's pull up
4 Exhibit 5539.

5 And, Your Honor, may we display? This is in
6 evidence.

7 THE COURT: Yes.

8 MR. ROGERS: Let's go to page 10. And can you pull
9 that top paragraph out, please. And -- well, let's look at
10 that first.

11 BY MR. ROGERS:

12 Q So are we back to looking at the Failure Investigation
13 Report?

14 A Yes.

15 Q And what is the purpose of this paragraph?

16 A Okay. This specific paragraph is talking about the
17 severity and scope of the failure investigation and during the
18 failure investigation one of the things we observed is that
19 the number of caudal migrations that were asymptomatic are
20 most of the caudal migrations were asymptomatic. So putting
21 them together with the cephalad migration was -- we -- the
22 decision was that it was best to separate them out so we could
23 really understand specifically what type of migration was
24 occurring, if it was cephalad or caudal. And so that was the
25 decision here is that we decided to break those out so we

DIRECT EXAMINATION (CONTINUED) - SHARI O'QUINN

13:18:55 1 could focus more on the specific type of migration.

2 Q So following this particular report, were cephalad
3 migration and caudal migration separated out for purposes of
4 tracking and trending?

13:19:11 5 A Yes.

6 Q And over the course of time you were at Bard, did Bard
7 continue to track and trend those two complications with their
8 IVC filters?

9 A Yes, we did. That's what that quality review board
13:19:25 10 meeting, that was the forum for which those would be reported
11 to the executive leadership on a regular basis and were
12 reviewed during those meetings.

13 Q As part of the process of preparing this Failure
14 Investigation Report, did the team that was investigating
13:19:41 15 caudal migration make a determination as to whether any
16 remedial action ought to be taken?

17 A Yes. That was -- we were continuously making that
18 assessment of whether any action was needed.

19 Q And as far as you are aware, did Bard ever make any
13:20:05 20 determination during your tenure there that the risks of the
21 G2 filter outweighed the benefit?

22 A No, it did not.

23 Q And during your tenure at Bard, did you believe that the
24 G2 filter provided a valuable therapeutic benefit for certain
13:20:24 25 patients?

CROSS-EXAMINATION - SHARI O'QUINN

13:20:25 1 A Absolutely. We believed the benefits outweighed the risk
2 and it provided an important need for the patients at risk of
3 pulmonary embolism.

4 MR. ROGERS: Thank you. I don't have any further
13:20:34 5 questions for you at this time.

6 THE COURT: Cross-examination.

7 MR. O'CONNOR: Yes. Thank you.

8 C R O S S - E X A M I N A T I O N

9 BY MR. O'CONNOR

13:20:53 10 Q Hello, Ms. O'Quinn. I'm Mark O'Connor.

11 A Hi, Mark.

12 Q Nice to see you today. Thank you for coming down.

13 Let me just talk to you for a moment about the FDA.

14 I think you agree that the FDA operates on an honor
13:21:05 15 system; correct?

16 A Could you clarify what you mean by honor system?

17 Q I can go to your testimony from previous, if you would
18 like.

19 The FDA relies on medical device companies to provide
13:21:21 20 truthful and accurate information; right?

21 A Yes.

22 Q And if the medical device company like Bard doesn't, then
23 that would be a breach of that honor system that the FDA
24 expects; right?

13:21:35 25 A It's important to always be honest and transparent with

CROSS-EXAMINATION - SHARI O'QUINN

13:21:38 1 FDA.

2 Q Because if a medical device company isn't honest and
3 transparent, the system won't work. Do you agree with that?

4 A I believe it's critical that we're honest and transparent,
13:21:48 5 yes.

6 Q Thank you.

7 Now, we talked -- you talked to Mr. Rogers about a
8 number of things. But the first thing I'd like to talk to
9 you, kind of go backwards and talk about this panel of experts
10 you met with in Chicago on June 1, 2006. Okay?

11 A Okay.

12 Q All those doctors that you referred to that were on
13 Exhibit 5537, those were all key opinion leaders of Bard;
14 correct?

13:22:25 15 A Not necessarily of Bard, but they were key opinion leaders
16 who placed vena cava filters.

17 Q They were paid consultants by Bard; true?

18 A I don't know if they were paid. I wasn't involved in
19 paying them.

13:22:38 20 Q Dr. Trerotola was a member; right?

21 A I believe Dr. Trerotola was present, yes.

22 Q And you're aware he was a paid consultant by Bard; true?

23 A I cannot verified who was paid or not. I have no
24 knowledge of who was paid. I was not involved in the -- any
13:22:55 25 consulting arrangements.

CROSS-EXAMINATION - SHARI O'QUINN

13:22:57 1 Q Dr. Morris, Dr. Christopher Morris, was present at that
2 meeting; correct?

3 A I don't know about Christopher Morris. I'd to have look
4 at the list. I don't recall his name.

13:23:19 5 MR. O'CONNOR: Let's go Exhibit 5537, Felice, to page
6 number 2.

7 BY MR. O'CONNOR:

8 Q You see Doctors John Kaufman, Tom Kinney. See Chris
9 Morris?

13:23:37 10 A Yes, his name is on here.

11 Q If Dr. Morris came in and testified that he had previously
12 been retained by Bard as a paid consultant, you would have no
13 reason to disagree, would you?

14 A I have no knowledge of who was paid.

13:24:00 15 MR. O'CONNOR: Felice, put up Exhibit 5536, please.

16 BY MR. O'CONNOR:

17 Q Now, earlier you talked about the Chicago meeting on
18 June 1, 2006 and there were people there from Bard to record
19 what happened and what was said at that meeting; correct?

13:24:18 20 A Yes.

21 Q And those were put into a writing and kept in the ordinary
22 course of Bard's business; right?

23 A Yes.

24 Q And what we're looking at is Exhibit 5536 that summarizes
13:24:30 25 what happened at the meeting at O'Hare Airport; right?

CROSS-EXAMINATION - SHARI O'QUINN

13:24:35 1 A Could I see the second page?

2 Q Sure.

3 A And could I see the last page.

4 Okay. Yes, that appears to be the document.

13:24:50 5 MR. O'CONNOR: Move for admission of 5536.

6 MR. ROGERS: No objection, Your Honor.

7 THE COURT: Admitted.

8 (Exhibit 5536 admitted.)

9 MR. O'CONNOR: May we publish Your Honor?

13:25:00 10 THE COURT: Yes.

11 BY MR. O'CONNOR:

12 Q Ms. O'Quinn, I noticed earlier when you and Mr. Rogers
13 were talking about the Failure Investigation Report -- you
14 recall talking about that; right?

13:25:11 15 A Yes.

16 Q And some of the comments from physicians at this meeting
17 were put into this report; right?

18 A Yes.

19 Q But as you can see, there's more comments that weren't
13:25:20 20 included in the Failure Investigation Report; true?

21 A Yes.

22 Q So let's look at Fracture.

23 MR. O'CONNOR: Felice, could you highlight

24 "Fracture."
25

CROSS-EXAMINATION - SHARI O'QUINN

13:25:33 1 BY MR. O'CONNOR:

2 Q Doctors at that meeting told Bard that they expected as
3 close to possible to zero percent for fractures; correct?

4 A Yes, that's the desire was to continue to make
13:25:48 5 improvements to the device to get to the rate to close --

6 Q My question is it says here right this is referring to
7 doctors comments; true?

8 A Yes.

9 Q It says "Expect as close as possible to zero percent."
13:26:00 10 Did I read that correctly?

11 A Yes.

12 Q Thank you. And at the bottom "Physician" -- last bullet
13 point, "Physicians talked more about concerns about fracture."

14 MR. O'CONNOR: Let's go to the last bullet point.

13:26:17 15 BY MR. O'CONNOR:

16 Q Here's what physicians told Bard: "Physicians are more
17 comfortable with a small PE that is asymptomatic than a
18 fracture."

19 Did I read that correctly?

13:26:31 20 Did I read those words correctly?

21 A Yes.

22 Q Thank you.

23 MR. O'CONNOR: Let's put up Exhibit 2248, Felice.

24 BY MR. O'CONNOR:

13:26:51 25 Q Now, you talked about this document before, but --

CROSS-EXAMINATION - SHARI O'QUINN

13:26:54 1 MR. O'CONNOR: Let's go to page 20, Felice.

2 May I publish, Your Honor? Exhibit 2248. I think

3 it's in evidence.

4 THE COURTROOM DEPUTY: It's in.

13:27:04 5 THE COURT: Yes, you may.

6 MR. O'CONNOR: Felice, can we quickly go to page 20.

7 BY MR. O'CONNOR:

8 Q Natalie Wong, you knew her; correct?

9 A Yes.

13:27:13 10 Q She was a new product development quality engineer; right?

11 A Yes.

12 Q You're not an engineer; true?

13 A No, I'm not an engineer.

14 Q And Natalie Wong, as you understood, put together these

13:27:24 15 studies regarding G2 caudal threshold; correct?

16 A Yes.

17 Q And one thing you know, that the SIR guidelines are not

18 intended to be standards or acceptable thresholds for the

19 medical device industry. You understand that; true?

13:27:40 20 A They are one point of reference.

21 Q My question is different. Are you aware that Dr. Grassi

22 has testified they're not intended to be industry standards?

23 Are you aware of that, yes or no?

24 MR. ROGERS: Objection, Your Honor. Exceeds the

13:27:54 25 scope.

CROSS-EXAMINATION - SHARI O'QUINN

13:27:57 1 MR. O'CONNOR: There was testimony about SIR
2 guidelines. Quite a bit, as a matter of fact.

3 THE COURT: I don't remember her mentioning SIR
4 guidelines.

13:28:06 5 MR. O'CONNOR: She was talking about industry
6 standards, I thought. And it was referenced in some
7 documents.

8 THE COURT: Objection is sustained.

9 MR. O'CONNOR: All right.

13:28:16 10 BY MR. O'CONNOR:

11 Q There was no testing of caudal migration of the G2 before
12 it was launched; true?

13 A Could you repeat that?

14 Q Sure. Bard didn't test the G2 for caudal migration before
13:28:29 15 the filter was launched; correct?

16 A We tested for migration -- the standard migration
17 resistance testing, but we were not aware of caudal migration
18 at that time.

19 Q So let me make sure you and I are on the same page.

13:28:44 20 Before the launch of the G2, Bard did not test the G2 for
21 caudal migration. Yes or no?

22 A Bard had never seen caudal migration before.

23 Q So is the answer to my question no, they did not test?

24 A No, we did not test. We were not aware of caudal
13:28:57 25 migration.

CROSS-EXAMINATION - SHARI O'QUINN

13:28:58 1 Q And, as you can see here, Natalie Wong on 2248.20 circled
2 those 3s and wrote the words "unacceptable risk per FMEA type
3 III above threshold." Did I read those words correctly?

4 A The words is correct, but the context is very important.

13:29:19 5 Q Ma'am, my only question is did I read that correctly.

6 A The words are correct, but that doesn't mean unacceptable
7 clinical risk.

8 MR. O'CONNOR: Move to strike as nonresponsive.

9 THE COURT: Please respond, if you would. If you
13:29:33 10 can't answer yes or no, you can tell him you can't answer yes
11 or no. But if you can, please answer.

12 Reask the question.

13 BY MR. O'CONNOR:

14 Q My question is, did I read those words correctly in this
13:29:40 15 document on page 20? Yes or no, please.

16 A You read the words correctly, yes.

17 Q Thank you.

18 And are you aware that Natalie Wong testified that
19 those were -- findings were alarming to her? Have you been
13:29:54 20 told that?

21 A I'm not aware of anything from Natalie that she would have
22 testified.

23 Q By the way, is Bard paying you for your time here?

24 A I have not been paid for my time here. I -- we had an
13:30:08 25 agreement that I may be compensated for some of the time I

CROSS-EXAMINATION - SHARI O'QUINN

13:30:11 1 have to take off from work to be here.

2 Q You've been compensated by Bard before; correct?

3 A Minimal amounts, yes.

4 Q And you have spent time with Bard lawyers before you came
13:30:23 5 here today; true?

6 A A couple of hours.

7 Q How many?

8 A Maybe three hours.

9 Q Thank you.

13:30:42 10 Let's go to Exhibit 6046.

11 Now, Ms. O'Quinn, this is another Medical Monitor
12 Adjudication Meeting Minutes dated August 28, 2006. Do you
13 see that?

14 A Yes, I do.

13:31:04 15 Q And you testified that these are the -- this is the --
16 this is a document that would come to Bard and be reviewed at
17 Bard; correct?

18 A Yes.

19 MR. O'CONNOR: Move -- I believe this is in evidence.
13:31:14 20 6046?

21 THE COURT: It is not.

22 MR. O'CONNOR: Move for admission into evidence, Your
23 Honor.

24 MR. ROGERS: No objection.

13:31:22 25 THE COURT: Admitted.

CROSS-EXAMINATION - SHARI O'QUINN

09:25:03 1 (Exhibit 6046 admitted.)

2 MR. O'CONNOR: And let's go to page 2.

3 And Felice, if you could highlight in that first main
4 paragraph "Dr. Kandarpa expressed."

13:31:43 5 Oh. May I publish, Your Honor?

6 THE COURT: Yes, you may.

7 MR. O'CONNOR: Can you highlight that sentence,
8 please.

9 BY MR. O'CONNOR:

13:32:06 10 Q And here's what these minutes state, and I'll read them to
11 you and you tell me if I read these words correctly:

12 "Dr. Kandarpa expressed concern about the number of reported
13 tilts hitting approximately 20 percent and thought that Bard
14 may want to closely evaluate this."

13:32:22 15 Now, did I read that correctly?

16 A Yes. And we responded.

17 Q Did I read it correctly, ma'am?

18 A Yes.

19 Q Thank you.

13:32:29 20 MR. O'CONNOR: And, Felice, if you could go down to
21 the next paragraph.

22 That's good.

23 BY MR. O'CONNOR:

24 Q The sentence I'd like us to look at, Ms. O'Quinn, is

13:32:53 25 "Dr. Kandarpa wanted to know if we were concerned that almost

CROSS-EXAMINATION - SHARI O'QUINN

13:32:58 1 50 percent of patients have reported AE," adverse events, "and
2 SAE," serious adverse events.

3 Did I read that correctly?

4 A Yes, but those are not all device related.

13:33:11 5 Q Did I read that correctly?

6 A Yes.

7 Q Thank you.

8 MR. O'CONNOR: Felice, put up Exhibit 704, please.

9 BY MR. O'CONNOR:

13:33:30 10 Q This is also entitled Bard EVEREST Medical Monitor
11 Adjudication Meeting Minutes dated August 28, 2006. Do you
12 see that?

13 A Yes.

14 MR. O'CONNOR: Move for admission.

13:33:41 15 THE WITNESS: I don't know that those were --

16 BY MR. O'CONNOR:

17 Q Excuse me.

18 A I see the minutes but I don't know -- these are not a Bard
19 document.

13:33:48 20 THE COURT: Hold on.

21 MR. O'CONNOR: I'm going to move for admission, Your
22 Honor.

23 THE COURT: Yes.

24 MR. ROGERS: Your Honor, 602.

13:33:57 25 THE COURT: Well, are you concerned about

CROSS-EXAMINATION - SHARI O'QUINN

1 authentication of the document?

2 MR. ROGERS: Yes, Your Honor. And as well as the
3 witness' knowledge.

4 THE COURT: Right. But that doesn't -- witness's
5 knowledge doesn't go to admissibility. You're concerned she
6 can't authenticate it?

7 MR. ROGERS: That's correct, Your Honor.

8 THE COURT: I think you need to ask additional
9 foundation questions.

10 BY MR. O'CONNOR:

11 Q You testified earlier, I thought, in response to
12 Mr. Roger's questions, these minutes only came to Bard and
13 Bard would review them and even review them to see if they had
14 signatures or not; correct?

15 MR. ROGERS: Objection, Your Honor. Same question.

16 THE COURT: Overruled.

17 BY MR. O'CONNOR:

18 Q That was your testimony as I understood it. Did I
19 understand your testimony correctly?

20 A Yes, we would review them.

21 Q And so documents -- these minutes would come to Bard and
22 be routinely reviewed; true?

23 A If we received them we would review them to see if there's
24 signatures, so I would need to see if this document has a
25 signature on it.

CROSS-EXAMINATION - SHARI O'QUINN

13:34:52 1 Q I can tell you this, that it doesn't. But it is a
2 document that's been produced in this litigation. And as I
3 understand your testimony, it was not unusual to receive
4 unsigned documents. Did I understand your testimony
13:35:05 5 correctly?

6 A No. The -- if it was unsigned, it would be verified if it
7 was authentic. And if it's not signed, I can't verify if it's
8 authentic.

9 MR. ROGERS: Your Honor, may we have a brief sidebar
13:35:18 10 about this?

11 THE COURT: Yes.

12 Stand up, if you like, ladies and gentlemen.

13 (Bench conference as follows:)

14 MR. ROGERS: Your Honor, the document that is on the
13:35:39 15 screen is an unsigned minute meeting. That was introduced by
16 BPA not Bard.

17 THE COURT: I gathered that. Why are we at sidebar?

18 MR. ROGERS: Because I don't think this witness can
19 sufficiently lay a foundation for the admission --

13:35:55 20 THE COURT: I understand that. But I don't think we
21 need to discuss that at sidebar just for purposes -- I
22 understand she just said she can't authenticate it. Were you
23 going to ask any other follow-up questions?

24 MS. SMITH: The document that just came into evidence
13:36:06 25 is the exact same document that's unsigned. It is the --

CROSS-EXAMINATION - SHARI O'QUINN

13:36:11 1 they're the same meeting minutes. Only thing that's different
2 is a sentence that has been --

3 THE COURT: But if she can't authenticate this as a
4 document that Bard ever received, what is the basis for
13:36:23 5 admitting it into evidence?

6 We have a three lawyer rule here. Go ahead.

7 MR. LOPEZ: No, they were there. We had a 30(b)(6)
8 deposition of someone from BPA who authenticated all these
9 documents. You know that.

13:36:34 10 THE COURT: But the fact it's a BPA document doesn't
11 make it admissible.

12 MR. LOPEZ: No, no, but it's been authenticated by
13 BBA as a business document.

14 THE COURT: It has to happen in this trial. It has
13:36:45 15 to be authenticated in this trial. Evidentiary rulings in
16 this trial are based on the evidence that occur in this
17 courtroom.

18 MR. LOPEZ: I understand that. I can show you the
19 testimony.

13:36:55 20 THE COURT: Well, but that testimony hasn't been
21 given in this courtroom, so this document is unauthenticated.

22 MR. LOPEZ: Your Honor, this was -- this document was
23 not produced by BBA to us, this was produced by Bard as their
24 records.

13:37:11 25 MS. SMITH: And they have a note --

CROSS-EXAMINATION - SHARI O'QUINN

13:37:12 1 MR. LOPEZ: They have Bates stamp. We didn't get
2 this from BBA, we got this from Bard's production.

3 THE COURT: What's your response?

4 MR. ROGERS: I can answer. A subpoena was sent to
13:37:21 5 BBA for their documents, and since this was a confidential
6 relationship between BBA and Bard, BBA provided the documents
7 to Bard first so they could redact any information that they
8 felt like was appropriate that needed to be redacted. Bard
9 then provided the documents to Plaintiffs' counsel.

13:37:40 10 These are BBA's documents, they're not Bard's
11 documents.

12 THE COURT: Well, they can produce them, but that
13 doesn't mean they were kept in their records.

14 MR. LOPEZ: Your Honor, we already have testimony
13:37:54 15 from Dr. Kandarpa and we've seen documents the relation
16 between Bard and BBA, they were agents. They worked on
17 this --

18 THE COURT: Here's the problem. There's been no
19 evidence in this courtroom that the document you want to move
13:38:07 20 into evidence was ever seen by Bard. Nobody's testified to
21 that.

22 MS. SMITH: I can --

23 THE COURT: Even if there's a sentence different,
24 there's no evidence that the different version has ever been
13:38:20 25 seen by Bard.

CROSS-EXAMINATION - SHARI O'QUINN

13:38:21 1 What evidence have I heard that says that in this
2 courtroom?

3 MR. LOPEZ: Well, okay, here's the point. She said
4 she got these minutes. Has a BPV file stamp on it. This one
13:38:36 5 has BBA file stamp on it. Why is this the one Bard got and
6 this is not the one Bard got?

7 THE COURT: You might think she should know it, but
8 she's just testified she doesn't. So I can't read her mind
9 and say she's wrong, she really knows it, and that's
13:38:51 10 sufficient foundation.

11 MR. LOPEZ: Why would that not be a business record
12 exception to this document if it was a Bard --

13 THE COURT: If you could lay foundation under 803(6)
14 that this was created at Bard, kept in the ordinary course of
15 business by people with knowledge, it will come in against a
13:39:02 16 hearsay objection under 803(6).

17 MR. LOPEZ: Let me ask, why would it haven't to be
18 created by Bard? If it's one of their agents -- I forget the
19 code section. That was produce -- that's a Bard
13:39:18 20 representative. This is a meeting minutes where Bard attended
21 of the agent --

22 THE COURT: My point is this, Mr. Lopez. Again, you
23 have to present evidence of foundation for it to be admitted.

24 MR. LOPEZ: Okay.

13:39:29 25 THE COURT: This witness has said she can't

CROSS-EXAMINATION - SHARI O'QUINN

13:39:31 1 authenticate it. If you think another witness can, put the
2 witness on and we'll -- we'll overcome the authentication
3 problem. But this witness has said she can't, and I have to
4 go on what this witness is saying if you're relying on it to
13:39:45 5 get it into evidence.

6 By the way, Counsel, everybody's been throwing around
7 the acronym BPA. Sometimes it sounds like VPA, sometimes it
8 sounds like BPA. I just saw it for the first time it's BBA.
9 That's never been explained to the jury. Somebody might want
13:40:04 10 to explain that to the jury.

11 MR. ROGERS: Thank you, Your Honor.

12 (The Court and the courtroom deputy confer.)

13 THE COURT: Apparently one of the jurors -- one of
14 the jurors just left and on the way out told Traci she isn't
13:40:26 15 feeling well, so we're going to wait a minute.

16 MR. LOPEZ: Sure.

17 (Bench conference concludes.)

18 THE COURT: You can remain standing, if you like,
19 ladies and gentlemen. We're just going to wait for a minute,
13:41:34 20 ladies and gentlemen, for Juror Number 4, see if she feels
21 better.

22 (Juror Number 4 entered the courtroom.)

23 THE COURT: Please be seated.

24 You may proceed, Mr. O'Connor.

13:45:42 25 MR. O'CONNOR: Thank you, Your Honor.

CROSS-EXAMINATION - SHARI O'QUINN

13:45:42 1 BY MR. O'CONNOR:

2 Q Ms. O'Quinn, I'm going to try to wrap it up here with a
3 few more questions.

4 The Failure Investigation Report that you talked
13:45:49 5 about earlier and the Health Hazard Evaluation report, those
6 are internal documents to Bard correct?

7 A Yes.

8 Q And you were involved in the beginning of the EVEREST
9 study; correct?

13:46:04 10 A Yes.

11 Q And the EVEREST study was for retrievability; true?

12 A Yes, that was the reason we conducted the study.

13 Q And the study looked at a set period of time for patients
14 to see whether the filter could be retrieved. Fair?

13:46:22 15 A There are nuances there that are really important because
16 it was for a set period of time, but that did not define the
17 retrievability period.

18 Q I understand that. My point was it was for a set period
19 of time.

13:46:34 20 A Yes.

21 Q And you left before the conclusion of the EVEREST study;
22 true?

23 A I don't recall the point of followup when I left Bard, but
24 I left before it was ultimately submitted to FDA.

13:46:49 25 Q And I take it that you weren't there when Bard had

CROSS-EXAMINATION - SHARI O'QUINN

1 meetings and slide presentations about what Bard learned from
2 the EVEREST study; true?

3 A We had discussions during the EVEREST study that I would
4 have been involved in. But after the study was over, I would
5 not have been involved in those.

6 MR. O'CONNOR: Felice, put up 1222. Page 6.

7 BY MR. O'CONNOR:

8 Q Let me just ask. I believe the testimony has been that
9 this slide presentation was in 2008. You were gone by then?

10 A Yes, I was gone by then.

11 MR. O'CONNOR: Display to the jury, Your Honor?

12 THE COURT: You may.

13 BY MR. O'CONNOR:

14 Q We're looking at 1222.

15 MR. O'CONNOR: And, Felice, go to page 6.

16 BY MR. O'CONNOR:

17 Q And I take it that you were not aware of any Venn diagrams
18 or things Bard did to try to tempt to discover the
19 relationship between failure modes. Fair?

20 A That was after I left the company.

21 Q Thank you.

22 MR. O'CONNOR: That's all I have --

23 MR. LOPEZ: Hold on. Page 14.

24 THE COURT: I don't think it is.

25 MR. O'CONNOR: Let's show page 14.

CROSS-EXAMINATION - SHARI O'QUINN

13:48:28 1 And, certainly --

2 MR. LOPEZ: Hold on, Mark.

3 MR. ROGERS: Objection, Your Honor. Foundation.

4 MR. O'CONNOR: Page 13. Excuse me.

13:48:38 5 BY MR. O'CONNOR:

6 Q And, Ms. O'Quinn, on the same point, you were gone before
7 Bard ever made a statement about how it could reduce the
8 number of filter complaints by eliminating failure modes;
9 correct?

13:48:55 10 A I've never seen this information.

11 MR. O'CONNOR: Thank you.

12 THE COURT: Redirect.

13 MR. ROGERS: No questions, Your Honor.

14 THE COURT: All right. Thank you, ma'am, you can
13:49:03 15 step down.

16 MS. HELM: Your Honor, at this time the defendants
17 call Dr. David Poll.

18 Your Honor, may I confer with plaintiffs' counsel
19 about one exhibit while Dr. Poll is coming in?

13:49:34 20 THE COURT: Yes, you may.

21 Ladies and gentlemen, while they're conferring let me
22 mention to you that we did have a discussion during the lunch
23 hour and we think we will get the case to you by the close of
24 the day on Wednesday, which would mean that you could then
13:49:51 25 start deliberating Thursday morning. So that's why we think

DIRECT EXAMINATION - DAVID POLL, MD

1 we can get the case finished this week.

2 All right. Next witness.

3 THE COURTROOM DEPUTY: Sir, if you'll please come
4 forward, stand right here and raise your right hand. State
5 spell your last name for the record.

6 THE WITNESS: David Poll, P-O-L-L, MD.

7 MS. HELM: May I approach to give this to Traci?

8 THE COURT: Yes.

9 MS. HELM: Your Honor, before we start I have one
10 housekeeping matter. Defendants move to admit Exhibit 4766,
11 which was an exhibit to Dr. Kuo's deposition and testimony.
12 I've conferred with plaintiffs' counsel and we believe there's
13 some additional redactions that we have no objection to, but I
14 would go ahead and move to admit that into evidence.

15 THE COURT: Any objection?

16 MS. SMITH: No objection.

17 THE COURT: All right. Admitted subject to
18 redaction.

19 (Exhibit 4766 admitted.)

20 MS. HELM: Thank you, Your Honor.

21 May I proceed?

22 THE COURT: You may.

23 **DAVID POLL, MD,**

24 called as a witness herein, after having been first duly sworn
25 or affirmed, was examined and testified as follows:

DIRECT EXAMINATION - DAVID POLL, MD

D I R E C T E X A M I N A T I O N

BY MS. HELM:

Q Dr. Poll, would you introduce yourself to the jury, please.

A Yes. Thanks. Dr. David Poll.

Q What is your profession?

A I am a practicing cardiologist and a cardiac electrophysiologist.

Q And, what are you here to tell the jury today?

A I'm here to tell the jury about my opinions with regard to Ms. Hyde from a cardiac standpoint.

Q Would you tell the jury your educational background, please.

A Sure. I attended Yale University for college, and then I attended University of Pennsylvania School of Medicine. Thereafter, I did internal medicine training at Yale New Haven Hospital, and then I returned to the hospital of the University of Pennsylvania for cardiology and electrophysiology training.

Q Would you tell the jury what the medical specialties of cardiology and cardiac electrophysiology involve, please.

A Sure. So cardiology involves the evaluation of individuals with heart disease, or potential heart disease. Evaluating symptoms, examining them, and establishing a diagnosis or differential diagnosis, and then embarking upon

DIRECT EXAMINATION - DAVID POLL, MD

1 treatment, which may include medications or device therapy or
2 referral for surgery.

3 Electrophysiology is a subspecialty of cardiology
4 that involves the evaluation and management of arrhythmias,
5 which are slow and fast heart rhythms.

6 Q And are you board certified in any specialty?

7 A I am. I'm board certified in internal medicine and
8 cardiovascular disease.

9 Q How long have you been practicing law, Dr. Poll?

10 A Practicing medicine.

11 Q Medicine. Oh, my goodness. I misspoke.

12 How long have you been practicing medicine?

13 A Medicine for 34 years.

14 Q And have you held any academic appointments?

15 A I have. I'm presently a clinical professor of medicine at
16 the University of Pennsylvania.

17 Q How long have you been teaching in the medical school
18 there?

19 A Well, throughout my 34 years of practice I've been
20 teaching in one form or another. Presently I teach residents,
21 some medical students, and formerly fellows in cardiology, but
22 no longer.

23 Q And you mentioned University of Pennsylvania. Where do
24 you currently practice medicine?

25 A So I practice at Pennsylvania Hospital, which is a

DIRECT EXAMINATION - DAVID POLL, MD

1 institution affiliated with the University of Pennsylvania.

2 Q And do you see patients on a regular basis?

3 A I do. I see about 60 to 70 patients a week, both in my
4 office and as well as in the hospital.

5 Q And describe generally what you do for the patients you
6 see on a weekly -- on a regular basis.

7 A Yeah. So pretty much in keeping with what I described the
8 practice of cardiology and electrophysiology. My practice has
9 an arrhythmia focus because I have the subspecialty training
10 in arrhythmia, but I see the full gamut of patients with heart
11 problems, chest pain, shortness of breath, palpitations,
12 fainting spells, heart failure. The full gamut. So I
13 evaluate those people and I treat them.

14 Q In what states are you licensed to practice medicine?

15 A In Pennsylvania and New Jersey.

16 Q Have you treated patients who have had or for whom you
17 have recommended an IVC filter?

18 A I have.

19 Q Do you have any training in engineering?

20 A I do not.

21 Q Do you have any training in the design, development, or
22 testing of medical devices?

23 A I do not.

24 Q And as a subset of that, do you have any training in the
25 design, development, or testing of IVC filters?

DIRECT EXAMINATION - DAVID POLL, MD

13:55:40 1 A I do not.

2 Q Are you a trained radiologist?

3 A I am not. However, as one can imagine, through 34 years
4 of practice, radiology plays a large part of evaluating
13:55:52 5 patients. I make a point of reviewing the images on my
6 patient. So I say I'm a cardiology expert but a decent
7 radiologist.

8 Q Have you ever implanted or retrieved an IVC filter
9 yourself?

13:56:07 10 A No, I have not.

11 Q Have you ever referred a patient to another doctor for the
12 placement of an IVC filter?

13 A I have.

14 Q What's the specialty of the doctor -- or specialties of
13:56:17 15 the doctor or doctors to whom you have referred patients for
16 the placement of an IVC filter?

17 A So either interventional radiologist, most commonly, but
18 there are also some cardiovascular interventional physicians
19 that place these filters.

13:56:31 20 Q You're not here today as an interventional radiologist,
21 are you?

22 A No, I am not.

23 Q Have you ever been involved in the decision of when or
24 whether to retrieve an IVC filter from a patient?

13:56:41 25 A I have.

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13:56:42 1 Q And, again, have you consulted with other specialties to
2 make that decision?

3 A So oftentimes I would make a decision that a patient
4 requires a filter, and then I would consult with the
13:56:54 5 implanting physician as to the propriety of that decision
6 and the planning for whether the filter should be retrieved.

7 Q In your practice when you have recommended order referred
8 a patient for the implant of an IVC filter, have you
9 recommended a permanent filter or retrievable filter?

13:57:18 10 A So now, most recently, uniformly I'm recommending
11 retrievable filters. Earlier on in my career I had
12 recommended some permanent filters. But as the landscape
13 changes, it becomes apparent that many patients do not require
14 indwelling filters and therefore the retrievability aspect of
13:57:42 15 it has become very attractive.

16 Q Have you, that you're aware of, encountered a patient who
17 had any complication or malfunction of an IVC filter?

18 A I have fortunately not had that in my practice.

19 Q Okay. Would you please tell the jury specifically what
13:57:58 20 you were asked to do by us in this case.

21 A Yeah. I was asked to review the records of Ms. Hyde from
22 the time she had her IVC filter implanted until the present
23 day looking at those records in terms of her medical
24 management from a cardiology perspective.

13:58:20 25 Q And the jury's heard this question asked a number of

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1 times, but were you paid for your work in this case?

2 A I was.

3 Q And do you know approximately how much you've been paid
4 for your work in this case regarding Ms. Hyde?

5 A I think, including my deposition appearance, I've been
6 paid approximately \$16,000.

7 Q And are you being paid for your time to be here today?

8 A I am.

9 Q And did you have to travel from Pennsylvania to be here?

10 A Yes, I did.

11 Q And how are you being paid today? Is it by the hour or a
12 different rate?

13 A May comment that I expected sunshine but I got rain.

14 I'm being paid \$10,000 to appear at trial, which is
15 meant to compensate for my having to come out here and close
16 my practice.

17 Q What did you review in your analysis? You told the jury
18 you were looking at Ms. Hyde's medical from a cardiologist
19 point of view. What did you review to form your opinions in
20 this case?

21 A So I reviewed the medical records. I reviewed the imaging
22 studies and looked at those myself. I reviewed a chronology
23 of events that was provided to me, which helped guide me as to
24 which specific records would have import from a cardiology
25 perspective. I reviewed expert reports on behalf of the

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13:59:52 1 plaintiff. And I reviewed deposition testimonies of
2 plaintiffs' experts Dr. Muehrcke and Dr. Hurst, as well as
3 deposition testimony of Ms. Hyde.

4 Q You mentioned a chronology that was provided to you. Did
14:00:10 5 you prepare that chronology?

6 A I did not, no.

7 Q Was that prepared by someone in my office?

8 A It was.

9 Q Did that chronology have any comments or analysis of the
14:00:17 10 medical records?

11 A No. It just had columns that showed the date, the
12 location of the clinical encounter, and the results of that
13 encounter. Strictly clinical with no comments.

14 Q You prepared to give your opinions as to your analysis of
14:00:35 15 Ms. Hyde's medical condition from a cardiologist point of
16 view?

17 A I am.

18 Q And specifically, what are those opinions?

19 A So it's my opinion that Ms. Hyde has a normal heart and
14:00:47 20 has no restrictions from a cardiology standpoint.

21 It's my opinion that she experienced no cardiac
22 events as a result of her IVC filter or it's fracture.

23 It's my opinion that she has no restriction of
24 activities that is required.

14:01:11 25 It's my opinion that she has no increased risk of

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1 arrhythmia or sudden cardiac death because she has a normal
2 heart.

3 Q Do you have an opinion as to whether she requires any
4 cardiac intervention such as a defibrillator?

5 A Right. So given that she has a normal heart and no
6 increased risk of arrhythmia or sudden death, she is not a
7 candidate for a defibrillator, in my mind.

8 Q And do you have an opinion as to whether she requires any
9 cardiac monitoring as a result of the filter fracture and
10 retrieval?

11 A Yes. So she requires no special cardiac monitoring at
12 this time.

13 Q And are these opinions that you're offering today being
14 offered to a reasonable degree of medical certainty?

15 A They are.

16 Q Before we talk about those opinions, let's go back and
17 identify some things that you are not talking about today.

18 Are you offering any opinions today about the Bard
19 filter at issue in this case?

20 A No, I'm not.

21 Q Are you offering any opinions about the regulatory path
22 used by Bard to have the filter cleared by the FDA?

23 A I am not.

24 Q Are you offering any opinions about the information for
25 use or warnings that accompanied the filter at issue in this

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1 case?

2 A I'm not.

3 Q Are you offering any opinions about which filter should
4 have been used by Ms. Hyde's implanting doctor?

5 A No, I am not.

6 Q Are you offering any opinions today whether Ms. Hyde was
7 an appropriate candidate for an IVC filter?

8 A I am not.

9 Q Are you offering any opinions today about whether her
10 filter should have been removed or the timing of that removal?

11 A Also, no, I am not.

12 Q Are you offering any opinions about the cause of any event
13 that occurred in Ms. Hyde's filter to fracture?

14 A No.

15 Q Okay.

16 Let's go back and talk about what you are offering
17 now that we've established that.

18 Do you know why Ms. Hyde received an IVC filter?

19 A I do.

20 Q And why did she receive a filter?

21 A So Ms. Hyde had experienced an episode of blood clot early
22 in her life in relation to birth control pills, I believe age
23 24. She subsequently presented with a blood clot in her lower
24 extremity that gave rise to a pulmonary embolus in 2009. And
25 then in 2011 she presented once again with blood clot in her

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14:03:36 1 lower extremity that gave rise to a large pulmonary emboli,
2 and at that point it was decided by her treating physicians to
3 implant the IVC filter to protect her from having an
4 additional pulmonary embolus which would have certainly
14:03:54 5 threatened her life.

6 Q From a cardiologist point of view, was there any
7 significance to Ms. Hyde having repeated DVT and pulmonary
8 embolism?

9 A Yes. So she demonstrated substantial risk of having
14:04:12 10 recurrent pulmonary emboli and recurrent blood clots in her
11 leg, so the IVC filter was to meant to protect her from
12 further pulmonary emboli.

13 Q And you talked about the medical records that you
14 reviewed. Did you review any medical records that predated
14:04:31 15 the implant of the filter?

16 A Well, I didn't recall -- I don't recall reviewing specific
17 records of -- that predated the filter. However, there were
18 multiple references as to her past medical history, which I
19 became aware of through those records.

14:04:49 20 Q After the filter was implanted, did she have additional
21 scanning that provided you information from a cardiologist
22 point of view?

23 A Yes. I believe she had the filter implanted in February
24 of 2011, and approximately two and a half weeks later she
14:05:06 25 presented with shortness of breath that concerned her, was

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14:05:10 1 similar to her symptoms that she had when she had the large
2 pulmonary embolus. So this prompted another CT scan of her
3 chest, which showed she still had blood clot present in her
4 lungs. On one side it was decreased in size, but it was still
14:05:27 5 present. So from a cardiac standpoint it shows me that the
6 filter implant was well-decided, that it was a good decision.

7 MR. O'CONNOR: Your Honor, this is not disclosed.
8 Move to strike.

9 MS. HELM: We'll move on, Your Honor.

14:05:42 10 THE COURT: All right.

11 BY MS. HELM:

12 Q Do you recall a March 5, 2012, treatment for Ms. Hyde
13 after the filter was implanted?

14 A I do. So --

14:05:54 15 Q Let me -- let me pull up an exhibit, Dr. Poll.

16 Would you pull up 8712, please.

17 And, Your Honor, I believe this is in evidence. May
18 I publish?

19 THE COURT: What's the number?

14:06:05 20 MS. HELM: 8712.

21 THE COURT: Yes, it is in evidence. You may publish.

22 BY MS. HELM:

23 Q Dr. Poll, is this a document you reviewed in forming your
24 opinions regarding Ms. Hyde?

14:06:19 25 A Yes, it is.

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14:06:27 1 MS. HELM: Scott, if you would go to the second page.
2 Under Review of Systems where it says Cardiovascular. Pull
3 that up.

4 BY MS. HELM:

14:06:36 5 Q Dr. Poll, can you see that?

6 A I can, yes.

7 Q And on her -- under her cardiovascular review of symptoms
8 it says intermittent palpitations. Do you see that?

9 A I do.

14:06:48 10 Q What are palpitations?

11 A Palpitation is a symptom that an individual experiences.
12 It is the sensation of either rapid or irregular heart rhythm.
13 It does not always correspond with a specific rhythm
14 abnormality but is the sensation one's hearts is beating too
14:07:08 15 rapidly or in a irregular fashion.

16 Q What are some of the causes of palpitation?

17 MR. O'CONNOR: Disclosure.

18 THE WITNESS: Palpitations --

19 THE COURT: Is that in the report, Ms. Helm?

14:07:20 20 MS. HELM: You know what, Your Honor, I'll move on.

21 We'll go on.

22 BY MS. HELM:

23 Q Dr. Poll, in March 12 -- in March of 2012 when Ms. Hyde
24 presented with card -- with a cardiovascular review of

14:07:37 25 symptoms of intermittent palpitations, was there any testing

DIRECT EXAMINATION - DAVID POLL, MD

1 done relating to those palpitations?

2 MR. O'CONNOR: Nondisclosure.

3 THE COURT: Ms. Helm?

4 MS. HELM: I'm looking, Your Honor. I apologize.

5 Your Honor, I'll move on.

6 THE COURT: All right.

7 BY MS. HELM:

8 Q After March of 2012, Dr. Poll, did you review some imaging
9 taken of Ms. Hyde in June, June 14, 2013?

10 A I did. I believe that was a CT scan that was performed
11 when she presented with abdominal pain. I believe the working
12 diagnoses was diverticulosis.

13 MR. O'CONNOR: Excuse me. Nondisclosure.

14 MS. HELM: Your Honor, it's listed in his medical
15 records. I'm not going to ask him any more questions about
16 it.

17 THE COURT: All right.

18 BY MS. HELM:

19 Q Dr. Poll, were you aware that in -- I'm sorry, I lost my
20 date. In May of 2014 there was imaging that showed Ms. Hyde's
21 filter had fractured?

22 A I am aware of that. Yes.

23 MS. HELM: Okay. And can we pull up 8721, please.

24 BY MS. HELM:

25 Q Is this a document you reviewed in evaluating Ms. Hyde

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1 from a cardiac point of view?

2 A Yes.

3 Q And is this a document that was -- that we were just
4 talking about that related to the finding of the strut in her
5 heart?

6 A Yes.

7 MS. HELM: Okay. And, Your Honor, at this time I
8 move to admit 8721.

9 MR. O'CONNOR: No objection.

10 THE COURT: Admitted.

11 (Exhibit 8721 admitted.)

12 MS. HELM: May I publish, Your Honor?

13 THE COURT: You may.

14 BY MS. HELM:

15 Q Dr. Poll, at the top under Number 1 would you tell the
16 ladies and gentlemen of the jury what symptoms Ms. Hyde
17 reported on May 16, 2014.

18 A So she complained of blood in her urine for a week and
19 that she was having pain in her back and lower abdomen.

20 Q Based on your review of the medical records, including
21 Exhibit 8721, in May of 2014 did Ms. Hyde complain of chest
22 pain or palpitations?

23 A She did not.

24 MS. HELM: Thank you. You can take that down.

25

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14:10:24 1 BY MS. HELM:

2 Q Dr. Poll, after Ms. Hyde was diagnosed as having the
3 fracture of the filter and it was found on the films in her
4 heart, did you review records indicating she went to see a
14:10:36 5 cardiologist?

6 A I did.

7 Q And do you recall when those dates were that she went to
8 see a cardiologist?

9 A I don't recall the specific dates but I think the fracture
14:10:47 10 was diagnosed in May of 2014 and then she self-referred to
11 Stanford in August of 2014. So --

12 Q Sometime in between?

13 A Correct.

14 Q Okay.

14:11:00 15 MS. HELM: Scott, can we pull up 8731, please.

16 Your Honor, I believe this is in evidence. May I
17 publish?

18 THE COURT: You may.

19 BY MS. HELM:

14:11:11 20 Q Dr. Poll, is this a document you reviewed in evaluating
21 Ms. Hyde from a cardiologist point of view?

22 A Yes.

23 Q Is this a treatment record for her with a cardiologist,
24 Dr. Shehane?

14:11:22 25 A Yes, it is.

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14:11:26 1 MS. HELM: And would you pull up "Review of Symptoms"
2 please -- "of Systems," please.

3 BY MS. HELM:

4 Q And, Dr. Poll, would you tell the ladies and gentlemen of
14:11:33 5 the jury what Ms. Hyde reported and what Dr. Shehane reviewed
6 relating to her cardiovascular systems.

7 A So she reported atypical chest pain. No palpitations,
8 dizziness, syncope, or leg swelling.

9 Q Do you recall did Dr. Shehane perform any testing or
14:11:54 10 evaluation to evaluate Ms. Hyde's chest discomfort?

11 A He ordered an echocardiogram.

12 MS. HELM: Scott, would you pull up 8730, please.

13 BY MS. HELM:

14 Q Is this the echocardiogram that --

14:12:11 15 MR. O'CONNOR: Excuse me. This was not on the
16 reliance list.

17 We'll, it's not discussed in the report, I should
18 say, excuse me.

19 MS. HELM: Your Honor, it's on page 3 of the report
14:12:28 20 in the last paragraph, the third line.

21 THE COURT: What's the date?

22 MS. HELM: The sentence begins "June" --

23 THE COURT: No; what's the date of the document?

24 MS. HELM: June 9.

14:12:43 25 THE COURT: Okay. Now where are you calling my

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14:12:44 1 attention?

2 MS. HELM: Page 3 of the report --

3 THE COURT: Okay. I see the reference.

4 MS. HELM: -- bottom paragraph. Sentence starting --

14:12:52 5 THE COURT: Hold on. I see it. Just a minute.

6 MR. O'CONNOR: That's all right. We withdraw the
7 objection.

8 THE COURT: All right. Go ahead.

9 MS. HELM: Thank you.

14:13:02 10 I've lost my train of thought, I apologize.

11 Your Honor, I move to admit 8730 at this time.

12 MR. O'CONNOR: Well, I just learned it's not on the
13 reliance list, Your Honor.

14 THE COURT: Is it on the reliance list, Ms. Helm?

14:13:38 15 MS. HELM: Your Honor. Page 12 of his report, Nevada
16 Heart and Vascular Center. Starting -- we only provided the
17 beginning bates number, but it's included in that group.

18 THE COURT: Your response, Mr. O'Connor?

19 MR. O'CONNOR: I'm being told that this is not
14:14:15 20 included in those set of documents.

21 THE COURT: Ms. Helm.

22 MS. HELM: Your Honor, I'll just ask the question and
23 withdraw my --

24 BY MS. HELM:

14:14:23 25 Q Dr. Poll, do you have a recollection of what the

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1 echocardiogram performed by Dr. Shehane showed relating to
2 Ms. Hyde's heart?

3 A I do. And I reviewed the echocardiogram myself. So she
4 had a normal heart, which meant that the valves were normal,
5 the chambers were normal, including the right and left
6 ventricles, that she had no fluid in the serac- -- sac
7 surrounding the heart.

8 MR. O'CONNOR: Objection. Nondisclosure.

9 THE COURT: Ms. Helm, is that in the report?

10 MS. HELM: Yes, Your Honor. That same paragraph
11 starting with the phrase "But her."

12 THE COURT: Objection's overruled.

13 MS. HELM: Thank you, Your Honor.

14 BY MS. HELM:

15 Q What is the significance of the negative echocardiogram?

16 A Well, it showed that there was no evidence of perforation
17 of the fragment that was visualized in the right ventricle.
18 In fact, the fragment was not visualized on this
19 echocardiogram and it showed that her heart was normal.

20 Q Following the treatment by Dr. Shehane in June of 2014, I
21 believe you testified that Ms. Hyde went to Stanford and was
22 treated by Dr. Kuo.

23 A Correct.

24 Q Did you have an opportunity to review Dr. Kuo's records --

25 A I did.

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14:16:05 1 Q -- from a cardiologist point of view?

2 A I did.

3 Q And was any testing related to Ms. Hyde's heart performed
4 at Stanford in August of 2014?

14:16:16 5 A I recall that the echocardiogram was repeated and once
6 again revealed that the heart was normal, the fragment was not
7 visualized, there was no evidence of perforation in the
8 fragment.

9 Q And this was an echocardiogram that was performed before
14:16:33 10 the retrieval process?

11 A Correct.

12 Q Did you also have an opportunity to review the retrieval
13 procedure report regarding Dr. Kuo's retrieval of both the IVC
14 filter and the strut from Ms. Hyde's heart?

14:16:47 15 A I did.

16 Q What of anything was significant from a cardiologist point
17 of view reported in that retrieval procedure note?

18 A It reported that the procedure went smoothly. It lasted
19 about an hour and 20 minutes. And that the fragment inside
14:17:09 20 the heart was easily retrieved on the first attempt, and
21 suggested that it was not embedded in the heart muscle to a
22 significant degree.

23 Q So after August of 2014, after Dr. Kuo retrieved the
24 filter and the strut, did you review additional medical
14:17:34 25 records relating to Ms. Hyde's care from a cardiologist point

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1 of view?

2 A I did.

3 Q And after the strut and the filter were removed in August
4 of 2014, did Ms. Hyde report to any of her treating physicians
5 any complaints of palpitations?

6 A She continued to have intermittent palpitations.

7 Q And do you have an opinion about whether those
8 palpitations were related to cardiac issues she had due to her
9 filter or the fragment that was removed from her heart?

10 A I do.

11 Q And what are your opinions?

12 A So Ms. Hyde had palpitations that preceded the fracture of
13 the IVC filter and she had palpitations during the time of the
14 fracture and she had palpitations after the IVC filter and
15 fragment were removed. So it was my opinion that she was
16 predisposed to palpitations and that the palpitations had
17 nothing to do with the events that occurred with the IVC
18 filter.

19 Q Thank you.

20 The jury's heard that after the filter was retrieved
21 in February of 2016 Ms. Hyde presented to an emergency room at
22 a hospital in Las Vegas with complaints of chest pain leading
23 up to her jaw. Do you recall those records?

24 A I do.

25 MS. HELM: Scott, would you pull up 8756, please.

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14:19:07 1 Your Honor, this is in evidence. May I publish?

2 THE COURT: Yes.

3 MS. HELM: Scott, would you pull up the "History of
4 Present Illness," please.

14:19:17 5 BY MS. HELM:

6 Q Dr. Poll, would you tell the ladies and gentlemen of the
7 jury the symptoms with which Ms. Hyde presented to the
8 emergency room in February of 2016.

9 A Yes. So she presented with chest pain that was localized
14:19:33 10 to the substernal region, which is right below the breastbone.
11 The quality was described as both dull and sharp, and lasted
12 on and off for approximately one day. There was radiation to
13 both jaws. And there was no associated shortness of breath.

14 Q And based on your review of medical records regarding
14:19:56 15 Ms. Hyde's care and treatment in February of 2016, did you see
16 any evaluation or analysis done by the doctors at the hospital
17 relating to her complaints of chest pain?

18 A Yes. So they evaluated her for myocardial infarction, or
19 heart attack, for which there was no evidence. They performed
14:20:17 20 a CT scan of the chest and that was normal. And they pursued
21 a pharmacologic stress test, which is a test performed to look
22 for blockages of the blood supply as a cause of the chest
23 pain, and that stress test was also normal.

24 Q From a cardiologist point of view, the testing and
14:20:41 25 evaluation that was performed in February of 2016 in the

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14:20:45 1 hospital in Las Vegas, what does that tell you about

2 Ms. Hyde's heart and the condition of her heart?

3 A These tests confirm her heart remains normal and was
4 normal at that time.

14:21:02 5 Q Do you have an opinion as to whether any chest pain
6 Ms. Hyde experienced in February of 2016 was in any way
7 related to the filter or the fragment retrieved from her
8 heart?

9 A I do.

14:21:14 10 Q And what is your opinion?

11 A So my opinion was that this was non-cardiac chest pain.
12 Her treating physicians thought it was an atypical form of
13 gastroesophageal reflux and it was my opinion it in no way
14 related to the fragment that had been removed from her heart.

14:21:34 15 Q Do you have an opinion from a cardiologist point of view
16 whether the strut that Dr. Kuo removed from Ms. Hyde's heart
17 caused any damage to her heart?

18 A I do.

19 Q And what is your opinion?

14:21:49 20 A It's my opinion that there is no evidence that any damage
21 had occurred.

22 Q You told the ladies and gentlemen of the jury that you had
23 the opportunity to review the reports and depositions of
24 Dr. Muehrcke and Dr. Hyde. And before we talk about those
14:22:05 25 opinions, you've mentioned you had training in

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1 electrophysiology.

2 A Correct.

3 Q What is electrophysiology?

4 A Electrophysiology is the evaluation and management of
5 individuals for rhythm abnormalities, both fast and slow.

6 Q Can you describe briefly how much of your practice over
7 the last 34 years has been related to the treatment of
8 arrhythmias?

9 A Sure. So over that time I would say maybe 50 percent of
10 my practice was involved with the evaluation and management of
11 arrhythmias.

12 Q Dr. Poll, has -- Dr. Muehrcke has offered an opinion in
13 this case that Ms. Hyde has an increased risk of developing
14 arrhythmia or sudden death from cardiac issues. Are you aware
15 of that opinion?

16 A I am.

17 Q Do you agree with that opinion?

18 A Not at all.

19 Q And why not?

20 A Because Ms. Hyde has a normal heart, which has been
21 demonstrated on numerous occasions with extensive testing.
22 And arrhythmias overwhelmingly occur in the population of
23 people that have abnormal hearts. She was never additionally
24 demonstrated to have a rhythm abnormality that would make one
25 think that she would need a defibrillator, but certainly,

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1 since there was no damage caused by the fragment, in my
2 opinion, and she still has a normal heart and would not have
3 an indication for a defibrillator or a risk of sudden death.

4 Q And the other opinion that Dr. Muehrcke offered was that
5 Ms. Hyde needs special annual cardiac monitoring. Are you
6 familiar with that opinion?

7 A I am.

8 Q Before I ask you about that opinion, since 2014 when the
9 strut was retrieved, in your review of the medical records
10 have any of Ms. Hyde's medical providers referred her or
11 recommended to her that she go see a cardiologist?

12 A No, they have not.

13 MR. O'CONNOR: Objection. Disclosure.

14 THE COURT: Is that in the report?

15 MS. HELM: Your Honor, his discussion of all of her
16 medical records throughout from 2014 through the present
17 are -- is in the report. But I have two questions. I'll just
18 move on in the interest of time.

19 THE COURT: Okay.

20 BY MS. HELM:

21 Q Your last opinion related to whether Ms. Hyde needs this
22 special cardiac monitoring. Do you have an opinion on that?

23 A Yes. She does not require any special monitoring.

24 Q And, again, Doctor, do you hold all of these opinions to a
25 reasonable degree of medical certainty that you've given

CROSS-EXAMINATION - DAVID POLL, MD

14:24:36 1 today?

2 A I do.

3 MS. HELM: That's all I have. Thank you.

4 THE COURT: Cross-examination.

14:24:40 5 MR. O'CONNOR: Yes. Thank you.

6 C R O S S - E X A M I N A T I O N

7 BY MR. O'CONNOR:

8 Q Hello, Dr. Poll. I'm Mark O'Connor. How are you?

9 A Very well. Thanks.

14:24:57 10 Q You came all the way here from Pennsylvania?

11 A I did.

12 Q Were you expecting sunshine?

13 A I was completely expecting sunshine.

14 Q Sorry for the disappointment. We like this weather.

14:25:08 15 Let me start out with this point, Dr. Poll. As a
16 medical doctor, you, like all medical doctors, take an oath
17 called the Hippocratic oath; correct?

18 A Correct.

19 Q All it says that, first, doctors should do no harm; right?

14:25:22 20 A Correct.

21 Q And that's a very important oath and important rule for
22 doctors; correct?

23 A Correct.

24 Q And I imagine in your practice you use devices of
14:25:36 25 different types. I know you don't use filters. Correct?

CROSS-EXAMINATION - DAVID POLL, MD

14:25:39 1 A Correct.

2 Q And certainly is it fair to say that doctors should expect
3 medical device companies to put patient safety first for
4 doctors to fill that promise?

14:25:53 5 A Yes. It's my expectation that device companies and drug
6 manufacturers do that.

7 Q It's your expectation they put patient safety first.
8 Fair?

9 A Correct.

14:26:06 10 Q Thank you. Now, you told us that you were provided
11 medical records from pardon Bard; right?

12 A Right.

13 Q And a medical chronology that was prepared by somebody
14 else at the Bard attorneys' office?

14:26:21 15 A Yes.

16 Q You didn't prepare it?

17 A No. My understanding it was prepared by a nurse and it
18 was strictly a timeline of the clinical events that occurred
19 between 2011 and the present.

14:26:35 20 Q When you serve as an expert, I know you're a doctor first,
21 I appreciate that, but when you serve as an expert, you expect
22 the party that retained you to provide you with all important
23 information that may be relevant to your opinions; true?

24 A Within the scope of the question they're asking me, yes,
14:26:58 25 true.

CROSS-EXAMINATION - DAVID POLL, MD

14:26:58 1 Q Just so you and I are on the same page, you did not
2 receive any Bard internal documents to see what Bard was aware
3 of regarding filter fractures or migrations to patients'
4 hearts; true?

14:27:10 5 A True, I did not.

6 Q Now, you didn't examine Ms. Hyde, did you?

7 A I did not.

8 Q You see patients of your own, though; is that true?

9 A I do.

14:27:24 10 Q And I imagine you've seen a lot of patients over the
11 years.

12 A Correct.

13 Q And -- and a doctor who puts patient safety first, one
14 thing you do when you see your own patient, you meet with her
14:27:36 15 or him and talk to them and take a history; correct?

16 A Correct.

17 Q And a history is important to you because then you can
18 hear the patient talk to you about his or her concerns and
19 explain to you what's been going on; right?

14:27:49 20 A Right.

21 Q And you know that Mrs. Hyde had those conversations with
22 doctors, including Dr. Kuo; right?

23 A Right.

24 Q And she told Dr. Kuo after he had questioned her about
14:28:02 25 problems that she had had over the years; right?

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14:28:06 1 A Right.

2 Q Including fluttering and palpitations.

3 A Right.

4 Q I take it because you're not a radiologist, you didn't

14:28:14 5 examine the specific imaging to look at exactly when this

6 filter fractured; is that fair?

7 A Well, I reviewed reports of all of her imaging. I did

8 briefly glance at them, but I'm not a radiologist, and I'm

9 confident that I know when the fracture occurred.

14:28:31 10 Q Okay. But in terms of how it fractured, what other parts

11 of the filter did, that was not -- well, the perforations were

12 not part of your opinions; correct?

13 A In the inferior vena cava you mean?

14 Q Yes, sir. You didn't mention them in your report; true?

14:28:53 15 A As far as I recall, no.

16 Q Okay. Thank you.

17 Now, you said that the filter fragment to the heart

18 was not embedded in the heart muscle. Did I understand that

19 correctly?

14:29:05 20 A Yes.

21 Q It was free floating?

22 A No. I just said it was easily retrievable, which implies

23 that it was not seriously embedded in the heart muscle.

24 Q But you're not eliminating the prospect that that filter

14:29:17 25 had -- that strut had the capability of embedding,

CROSS-EXAMINATION - DAVID POLL, MD

1 penetrating, or going through the heart to another location;
2 right?

3 A You mean before it was extracted?

4 Q Yes. I mean a filter that is not embedded -- a strut had
14:29:36 5 that capability; true?

6 A It can have that capability, yes.

7 THE COURT: We're going to break at this point,
8 Mr. O'Connor.

9 We will resume, ladies and gentlemen, at a quarter to
14:29:45 10 the hour. We'll excuse you.

11 (Recess taken from 2:30 to 2:44. Proceedings resumed in
12 open court with the jury present.)

13 THE COURT: Thank you. Please be seated.

14 You may continue, Mr. O'Connor.

14:46:12 15 MR. O'CONNOR: Thank you, Your Honor.

16 BY MR. O'CONNOR:

17 Q Thank you, Dr. Poll, for coming back.

18 Dr. Poll, when you prepared your report, I take it
19 that you were very careful in how you worded it so that your
14:46:26 20 opinions could be accurately stated; correct?

21 A Yes.

22 Q And just in your practice, you rule in and rule out
23 various conditions. That's a differential diagnosis; correct?

24 A Correct.

14:46:41 25 Q And there are times when you can't rule out something

CROSS-EXAMINATION - DAVID POLL, MD

14:46:44 1 completely. Fair?

2 A Yes.

3 Q A differential diagnosis works when you have a list,
4 right, and you try to look at symptoms and other issues that
14:46:54 5 the patient raises -- raises. You look at tests and either
6 rule in or rule out a diagnosis; correct?

7 A Correct.

8 Q And if we look at your report at Exhibit 4643 --

9 MR. O'CONNOR: Could you just put it up for the
14:47:07 10 doctor, please, Felice. Go to page 4.

11 And, Felice, if you could, just the second to last
12 sentence, highlight it, and I'll read it with Dr. Poll.

13 Starting with "Her palpitations."

14 BY MR. O'CONNOR:

14:47:34 15 Q Now, here's what you said, Dr. Poll, and I just want you
16 to listen to it, make sure I've read this accurately, please.

17 "Her palpitations may have been due to the presence
18 of the filter arm in her right ventricle, but given their
19 presence before the filter fractured and their continued
14:47:51 20 presence after the removal of the filter, the palpitations
21 appear to be unrelated to the filter arm and more likely
22 related to something else, such as potentially anxiety or
23 stress."

24 Now did I read that correctly?

14:48:05 25 A You did.

CROSS-EXAMINATION - DAVID POLL, MD

14:48:06 1 Q Thank you. Now -- and one thing it appears you were
2 careful in the history, and all the palpitations that were
3 recorded came after the filter was implanted. Fair? If we
4 look at a timeline?

14:48:22 5 A Incorrect. She had palpitations -- oh. Palpitations I
6 noticed were in 2012, after the filter was implanted --

7 Q That's what I meant. Just after it implanted, if we did a
8 timeline, we could look at the date of implant when the filter
9 was implanted and that's when you saw evidence of

14:48:37 10 palpitations; is that fair?

11 A From what I reviewed, that's fair, yes.

12 Q Thank you. And let's -- I asked you earlier about health
13 hazard evaluations, which you didn't review in this case.
14 Internal Bard documents. And told me you did not receive
14:48:55 15 those. Fair?

16 A Correct, I did not receive those.

17 Q You understand that Bard has a medical director. That
18 makes sense to you, doesn't it?

19 A Sure.

14:49:06 20 MS. HELM: Your Honor, excuse me. I believe this
21 exceeds the scope of direct.

22 THE COURT: I don't know what the question is yet.

23 BY MR. O'CONNOR:

24 Q My question is this: You don't know what Dr. Ciavarella
14:49:18 25 or anybody else has discussed about the risks that a strut may

CROSS-EXAMINATION - DAVID POLL, MD

1 pose that fractures and goes to a patient's heart.

2 MS. HELM: Same objection, Your Honor.

3 THE COURT: Overruled.

4 THE WITNESS: Can you ask the question again, please.

14:49:35 5 BY MR. O'CONNOR:

6 Q Sure. I'll try to remember it.

7 A Thanks.

8 Q You don't know and have not read anything about what the
9 medical director at Bard has stated, Dr. Ciavarella, in terms
14:49:46 10 of what risk may exist from the fractured strut that embolizes
11 into a patient's heart. You have not seen what their
12 viewpoint is on that. Fair?

13 A I have not seen that, no.

14 Q Now, you have never retrieved a filter; true?

14:50:03 15 A True.

16 Q And you saw Dr. Kuo's procedure; correct?

17 A Correct.

18 Q And Dr. Kuo described his procedure as a complex
19 procedure; correct?

14:50:12 20 A It was only complex because of the catheters that are
21 required.

22 Q Dr. Kuo wrote "complex" in the procedure, didn't he?

23 A I'm explaining to you why he wrote "complex."

24 Q I didn't ask you why. Did he describe it as a complex
14:50:25 25 procedure?

REDIRECT EXAMINATION - DAVID POLL, MD

14:50:25 1 A Described as complex retrieval because to retrieve the
2 fragment in the ventricle you need to use more than one
3 catheter.

4 Q You have never done that type of procedure?

14:50:36 5 A I have not, no.

6 Q And certainly that could be a frightening procedure for a
7 patient; do you agree with that?

8 A Well, I think any procedure is frightening for a patient.
9 So is having life-threatening pulmonary emboli.

14:50:55 10 Q Thank you. You agree that the procedure, though, Dr. Kuo
11 did describe it as complex, and I think you've said why,
12 because he was using catheters to go into the right ventricle;
13 right?

14 A Right.

14:51:06 15 Q And just so you and I are on the same page, you have not
16 performed that type of procedure; right?

17 A Correct.

18 MR. O'CONNOR: That's all I have. Thank you.

19 THE COURT: Redirect.

14:51:19 20 MS. HELM: Briefly, Your Honor.

21 R E D I R E C T E X A M I N A T I O N

22 BY MS. HELM:

23 Q Dr. Poll, Mr. O'Connor asked you about a timeline that was
24 prepared by a nurse from my firm. How did you use that
14:51:28 25 timeline?

REDIRECT EXAMINATION - DAVID POLL, MD

14:51:28 1 A So I used that to get a general impression of the
2 chronology of events, and then when I saw there was a
3 cardiac-related matter I would retrieve the original medical
4 records to base my opinion on.

14:51:39 5 Q Did you review the medical records yourself?

6 A I did.

7 Q Did you rely on any summary of the medical records
8 provided to you by anyone?

9 A No.

14:51:48 10 Q Mr. O'Connor also asked you about things that could have
11 happened with the filter -- with the strut in Ms. Hyde's
12 heart. Do you recall those questions?

13 A I do.

14 Q Did any of those things happen to Ms. Hyde?

14:52:00 15 A They did not.

16 MS. HELM: No further questions, Your Honor.

17 THE COURT: All right. Thank you, sir, you can step
18 down.

19 MR. CONDO: Your Honor, we recall Mr. Andrzej
14:52:27 20 Chanduszeko.

21 THE COURTROOM DEPUTY: If you would please come
22 forward, Mr. Chanduszeko.

23 Please raise your right hand, sir.

24 If you could state your name spell it for the record
14:52:45 25 and the jury.

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

1 THE WITNESS: Andrzej Chanduszek. A-N-D-R-Z-E-J
2 C-H-A-N-D-U-S-Z-K-O.

ANDRZEJ CHANDUSZKO,

3
4 called as a witness herein, after having been first duly sworn
5 or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

6
7 BY MR. CONDO:

8 Q Mr. Chanduszek, would you please introduce yourself to the
9 ladies and gentlemen of the jury and tell them where you work.

10 A My name is Andrzej Chanduszek. I'm an engineer and I work
11 at Bard Peripheral Vascular.

12 Q And how long have you worked with Bard Peripheral
13 Vascular?

14 A For the last 14 years.

15 Q And what's your current title or position with the
16 company?

17 A I'm a principal engineer.

18 Q Are you an engineer by training and experience?

19 A That's correct.

20 Q Where were you born, sir?

21 A I was born in Poland.

22 Q When did you first come to the United States?

23 A I came in 1989.

24 Q How old were you when you came?

25 A I was 24 years old.

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

14:54:05 1 Q And have you become a US citizen since then?

2 A Yes, I have.

3 Q Is English your first language?

4 A No. Polish is my first language.

14:54:17 5 Q Do you sometimes struggle with English phrases and terms?

6 A Just a little bit sometimes.

7 Q And how do you manage when you're struggling with an

8 English term or phrase that may be a little unfamiliar to you?

9 A One way is I could rephrase it in my own words to make

14:54:40 10 sure I understand correctly.

11 Q Let's tell the ladies and gentlemen of the jury a little

12 bit about your educational background. Where did you go to

13 school in Poland?

14 A So I studied environmental protection in Poland for four

14:54:54 15 years and then when I came to the US I studied mechanical

16 engineering at Northeastern University in Boston and I got a

17 bachelor degree of science.

18 Q And your BS was in what discipline, sir?

19 A It was mechanical engineering technology.

14:55:15 20 Q And where is Northeastern University located?

21 A It's in Boston, Massachusetts.

22 Q What year did you take your BS degree?

23 A It was 1997.

24 Q Why did you choose to study engineering and become an

14:55:30 25 engineer?

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

14:55:32 1 A So I wanted to be an engineer since I was a child. Math
2 and physics, these were always my favorite subjects and I also
3 like problem solving. So it became natural to me to follow
4 engineering path.

14:55:52 5 Q And in what you do at Bard Peripheral Vascular for the
6 last 14 years, does it involve problem solving?

7 A Yes, a lot of it.

8 Q Now, has most of your professional career since college
9 been in the medical devices field?

14:56:07 10 A Yes. 100 percent.

11 Q Why have you chosen to pursue a career in the medical
12 devices field?

13 A So before I went to school I worked at Massachusetts
14 General Hospital. It's a big hospital in Boston. I was
14:56:28 15 delivering medical equipment to hospital floors and patients,
16 and I saw a lot of sick people, some of them very sick. But I
17 also saw how the medical technology can make a great impact on
18 their lives and I wanted to be part of it.

19 So when I was at school, Northeastern had a co-op
14:56:55 20 program, which is like a full-time internship for six months,
21 and I asked my co-op advisor to see if she could get me in
22 touch with a medical company, and she did.

23 Q And who was or what was that medical company?

24 A It's NMT Medical.

14:57:15 25 Q And did you eventually go to work at NMT Medical?

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

14:57:19 1 A Yes. So when I graduated in 1997, they hired me
2 full-time.

3 Q Now, in your career as an engineer working in medical
4 devices, have you had any patents issued to you for medical
14:57:34 5 devices?

6 A Yes. In fact, all the patents I hold are for medical
7 devices.

8 Q And approximately how many patents are issued to you, sir?

9 A It's over 70, think. Probably 72.

14:57:50 10 Q And can you give the ladies and gentlemen of the jury some
11 idea of the types of products that are covered by or involve
12 the patents that have been issued to you?

13 A So some of the patents involve a patches that you can put
14 in a heart when someone has a hole. That's for my prior
14:58:08 15 company. And from Bard I have vena cava filters, stents,
16 stent grafts, angioplasty balloons. Things like that.

17 Q During your work at NMT, did you eventually come to work
18 on an IVC filter that is now known as the Recovery filter?

19 A Yes. So I worked under the direction of our senior
14:58:37 20 engineers. It was my first job after school.

21 Q Was Mr. Carr one of those more senior engineers whom you
22 worked under at NMT?

23 A Yes, that's correct.

24 Q Now, the ladies and gentlemen of the jury have heard some
14:58:50 25 testimony about the risks of IVC filters. And through your

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

1 work as an engineer over the past several decades with IVC
2 filters, do you have an understanding of the inherent risks
3 associated with those products?

4 A Yes, I do.

5 Q And have you ever -- have you always worked as an engineer
6 to reduce those risks as much as reasonably possible?

7 A Yes, I have.

8 Q And, in fact, when you go to work every day, is reducing
9 the risks of the products one of your primary objectives or
10 goals as an engineer?

11 MR. O'CONNOR: Objection. Leading.

12 THE COURT: Sustained.

13 BY MR. CONDO:

14 Q When you go to work everyday, do you have a primary goal,
15 sir?

16 A Yes. My primary goal is to make the device I'm working on
17 as safe as possible.

18 Q Let's talk, if we can, about your work at -- first at NMT.
19 What kinds of responsibilities did you have at NMT?

20 A So my main responsibility was to perform all kinds of
21 testing on filters.

22 Q And at some point did NMT sell its rights to the Recovery
23 filter to CR Bard?

24 A Yes, that's correct.

25 Q And did you eventually move from NMT to Bard?

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:00:15 1 A Yes, I did. About three years later.

2 Q And when you eventually moved to Bard from NMT, did you
3 have an opportunity to resume working on the Recovery filter
4 at Bard?

15:00:30 5 A So I'm not sure I understand the question because Recovery
6 filter was already --

7 Q It was on the market.

8 A -- developed.

9 Yes.

15:00:42 10 Q Okay. Let me back up, then.

11 When you moved to Bard, what filter did you become --
12 did you work on?

13 A G2 filter.

14 Q And what was your role in connection with the G2?

15:00:56 15 A So I had many roles. The main would be I did a lot of
16 testing, but also did a test method development. I did some
17 design work, both on the filter and delivery system. I also
18 worked on manufacturing fixtures.

19 Q Are you familiar with the design of the Recovery filter as
15:01:24 20 a result of your work at NMT?

21 A Yes, I am.

22 Q And are you familiar with the design of the G2 as a result
23 of your work at Bard?

24 A Yes, I am.

15:01:33 25 Q Let's go back and talk about your role in the development

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

1 of the Recovery filter at NMT.

2 What role did you have? How were you involved, sir?

3 A So, as I mentioned, the main role was I was running all
4 kinds of tests on the filter.

5 Q When you say all kinds of tests, can you give the ladies
6 and gentlemen of the jury some examples of the kinds of tests
7 that you were running at NMT on the Recovery filter.

8 A Yes. So, for example, I ran a migration test, probably a
9 radial test, also a fatigue test on the filter.

10 Q Are all those forms of bench tests?

11 A Yes, that's correct. These are all bench tests.

12 Q And the ladies and gentlemen of the jury have heard a lot
13 of testimony about bench testing. Are bench testing one way
14 to simulate the performance or assess the performance of a
15 product in a simulated environment?

16 A That is correct. That is an industry standard for
17 simulating physiological environment such as vena cava.

18 Q Now, if I can, I want to talk specifically about one test
19 that you did on the Recovery filter. You told us that you
20 were involved with testing -- fatigue testing on the Recovery
21 filter at NMT; correct?

22 A Yes, that's correct.

23 Q Let me show you --

24 MR. CONDO: Scott, can you pull up Exhibit 5233
25 please.

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

1 BY MR. CONDO:

2 Q Do you recognize the exhibit that's displayed on screen
3 before you, Exhibit 5233, Mr. Chanduszeko?

4 A Yes, I do.

5 Q Is that your name as the author of the document?

6 A Yes, that's correct.

7 Q Is that your signature?

8 A Yes, it is.

9 Q And is this a document that was prepared in the regular
10 course of business at NMT?

11 A Yes, it was.

12 MR. CONDO: Your Honor, we would offer Exhibit 5233.

13 MR. O'CONNOR: One moment.

14 Can we save see page 2, please.

15 No objection.

16 THE COURT: Admitted.

17 (Exhibit 5233 admitted.)

18 MR. CONDO: May we publish, Your Honor?

19 THE COURT: You may.

20 MR. CONDO: Thank you.

21 BY MR. CONDO:

22 Q Mr. Chanduszeko, at NMT what was an R&D standard operating
23 procedure document?

24 A Effectively a protocol for the tests. So it describes how
25 the test will be conducted.

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:04:19 1 Q And in this particular exhibit --

2 MR. CONDO: Scott, can you highlight the SOP title,
3 please.

4 BY MR. CONDO:

15:04:27 5 Q What procedure was being described for the test?

6 A EnduraTEC corrosion fatigue testing of RNF filters design
7 verification.

8 Q Thank you. And that is your signature on the Author line,
9 sir?

15:04:46 10 A Yes, it's mine.

11 MR. CONDO: If we can turn to page 2 of the Exhibit.
12 Scott, would you please highlight "The Purpose."

13 BY MR. CONDO:

14 Q Can you describe for the ladies and gentlemen of the jury
15 why you were evaluating ten years of equivalent of corrosion
16 and fatigue endurance of the Recovery filter in this test?

17 A So the fatigue of the filter -- filter's an implantable
18 device that's in the IVC and it's implanted for many years.

19 And while the vena cava deforms, effectively the filter is
15:05:30 20 also extends and contracts. Because it happens over many

21 millions of cycles it is absolutely critical to evaluate that
22 on the bench. And the ten years in particular is an industry
23 standard for this test. In fact, for most implantable
24 devices, but including also vena cava filters.

15:05:54 25 Q All right. Let's talk a little bit, if we can, about the

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:05:58 1 industry standard.

2 MR. CONDO: Scott, would you highlight the Reference
3 Documents, the first numbered item of the Reference Documents
4 on page 2 of the exhibit.

15:06:07 5 BY MR. CONDO:

6 Q Is that the industry standard that sets forth the ten-year
7 equivalence test?

8 A Yes, that's correct.

9 Q And is there a current equivalent test today or standard
15:06:26 10 today that covers both retrievable and permanent filters?

11 A Yes, there is.

12 Q And what is the duration equivalence of that standard?

13 A It's the same, it's ten years.

14 Q Can you describe for the ladies and gentlemen of the jury
15:06:46 15 how this test that's described in Exhibit 5233 was actually
16 performed.

17 A So the -- so because the duration is ten years and it's
18 based on breathing, so every single cycle is inhale and
19 exhale. And so based on the respiratory rate, one can

15:07:13 20 actually calculate how many cycles or how many times a person
21 is going to breathe every year. And then if you multiply it
22 by ten, then you're going to get the final number. And then
23 that number of cycles is executed during the test.

24 So the requirement per this protocol was 32 million
15:07:33 25 cycles. The test was actually we ran the test a little longer

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:07:38 1 to 36 million cycles just to make sure we pass the ten years
2 equivalency. And then at that point we stop the test and we
3 evaluated the filters to make sure that there were no
4 fractures and also to make sure there was no sign of
15:07:56 5 corrosion.

6 Q And were the filters actually deflected in this test?

7 A Yes. So there is a -- what we call a laser microammeter
8 that measures the distention of the tubes and the
9 measurements -- the requirements for the distention of the
15:08:18 10 filters was 1 millimeters. And because we wanted to minimally
11 meet that one-millimeter mark, the test was actually ran and
12 the measurements were from 1 to 1.7 millimeters.

13 Q And was a report prepared on the results of this testing?

14 A Yes, there was a report.

15:08:39 15 Q And were you involved in the preparation of that report?

16 A I believe so.

17 Q And was the report prepared in the ordinary course of
18 business of NMT?

19 A Yes, that's correct.

15:08:51 20 MR. CONDO: Your Honor, we would offer Exhibit 5234.

21 MR. O'CONNOR: No objection.

22 THE COURT: Admitted.

23 (Exhibit 5234 admitted.)

24 MR. CONDO: May we publish, Your Honor?

15:09:00 25 THE COURT: You may.

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:09:01 1 MR. CONDO: Scott, would you call up Exhibit 5234.
2 Can you highlight the title or technical report
3 title.

4 BY MR. CONDO:

15:09:15 5 Q Is this the report of the corrosion fatigue testing for
6 which you wrote the protocol that we just observed?

7 A Yes, it is.

8 Q All right. And is that your signature a little farther
9 down on the cover sheet, first page?

15:09:33 10 A Yes, it is.

11 Q If you would, Scott, would you turn to page 3.

12 And in the first full paragraph highlight just the
13 first sentence.

14 Over what period of time was the test run, sir?

15:10:03 15 A So I don't remember exactly, but it was several weeks.

16 Q And how many filter -- how many cycles were these filters
17 subjected to?

18 A According to the document, a little over 36 million
19 cycles.

15:10:22 20 Q Now, what pulmonary function provides or produces the
21 distention or the change in the diameter of the IVC filter?

22 A It's breathing.

23 MR. CONDO: If you'd turn to page 4, Scott.

24 Scott, can you highlight the Conclusion.

25

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:10:56 1 BY MR. CONDO:

2 Q What were the results of the test as memorialized in the
3 report, sir?

4 A "After the equivalent of 10 years of cyclic stress, the 16
15:11:11 5 RNF filters placed in a simulated physiological environment,
6 the filters did not experience any failure due to fatigue or
7 corrosion. There was no evidence of physical damage on any of
8 the filters."

9 Q Now, are you familiar with the engineering principles of
15:11:30 10 Nitinol -- or engineering characteristics of Nitinol?
11 Material characteristics.

12 A Yes, I am.

13 Q When you run a test of Nitinol filters to a ten-year
14 equivalence, does that provide engineering data that allows
15:11:43 15 you to project whether those filters will continue to perform
16 satisfactorily into the future?

17 A Yes, it does. In fact, it's not just for Nitinol, but for
18 most metals it's the same thing.

19 Q Now, did you end the test at the 36 million cycles?

15:12:04 20 A No. In fact, we did not.

21 Q How many additional cycles did you run these filters
22 through? Do you know?

23 A So, the filters were ran I believe over 400 million
24 cycles.

15:12:22 25 Q And what would be the equivalent in years of 400 million

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:12:27 1 cycles?

2 A So depending on the rates of respiration, probably
3 anywhere from 50 to 100 years.

4 Q Why did you keep running the test for an additional
15:12:43 5 300-plus million cycles if you had already achieved the
6 results you needed at 36 million cycles?

7 A I just want to make sure the device was robust.

8 Q And what did you observe of the filters after 400 million
9 cycles?

15:13:06 10 A We observed effectively the same thing we observed at
11 36 millions, meaning they were all intact and there were no
12 signs of corrosion.

13 Q And were the results of these tests memorialized in a lab
14 notebook?

15:13:22 15 A Yes, they were.

16 MR. CONDO: Scott, would you please pull up Exhibit
17 5022.

18 BY MR. CONDO:

19 Q Mr. Chanduszeko, do you recognize Exhibit 5022 as displayed
15:13:36 20 on your screen?

21 A Yes, I do.

22 Q And is that your name as the owner of this lab notebook?

23 A Yes, it is.

24 Q And was this lab notebook prepared by persons having
15:13:55 25 knowledge of the information contained therein?

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

15:13:58 1 A Yes.

2 Q And was it kept in the ordinary course of business at NMT?

3 A That's correct.

4 MR. CONDO: Your Honor, we would offer Exhibit 5022.

15:14:11 5 MR. O'CONNOR: No objection.

6 THE COURT: Admitted.

7 (Exhibit 5022 admitted.)

8 BY MR. CONDO:

9 Q Mr. Chanduszek --

15:14:18 10 MR. CONDO: May we publish, Your Honor?

11 THE COURT: You may.

12 BY MR. CONDO:

13 Q What's the purpose of memorializing test results in a lab
14 notebook --

15:14:29 15 A So this is pretty much engineering standard and it's a
16 standard for record keeping. So these results are effectively
17 memorialized and available for the future if anyone wanted to
18 look at them.

19 Q Does the lab notebook document each and every step taken
15:14:48 20 during the testing procedure?

21 A It might. It contains data and data measurements.

22 Q Thank you.

23 Now, let's talk about the G2.

24 And at some point after the FDA cleared the Recovery
15:15:10 25 filter and you came to Bard, you began to work on the G2;

DIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

1 correct?

2 A That is correct.

3 Q When was the development process started for the G2
4 filter?

5 A So it started sometime in early 2004.

6 Q And what was your role in that process?

7 A So my role was testing, test method development,
8 development of manufacturing fixtures. I did some design work
9 on both the filter and the delivery system. Manufacturing
10 fixtures. These kind of things.

11 Q Were you involved in building prototypes?

12 A Yes, I was.

13 Q Were you involved in testing prototypes?

14 A Yes, I was.

15 Q Were you involved in developing and building manufacturing
16 prototypes?

17 A Yes.

18 Q Are those sometimes referred to as jigs?

19 A Yeah. So these are fixtures that are used to set the
20 shape in the filter wire.

21 Q And Mr. Carr told us this morning about a saluting arm
22 fatigue test that was performed in connection with the G2
23 filter.

24 Was that a test method that you were involved in
25 developing?

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15:16:35 1 A Yes. I was the main contributor to that test.

2 Q At my request, have you reviewed a demonstrative exhibit
3 that depicts the differences between the Recovery and the G2
4 filter?

15:16:49 5 A Yes, I did.

6 Q And would the -- would the demonstrative help you explain
7 your testimony to the jury?

8 A Yes, it would.

9 MR. CONDO: Your Honor, we would request permission
15:17:01 10 to publish Exhibit 7875 as a demonstrative exhibit.

11 MR. O'CONNOR: We'd like to see it first.

12 MR. CONDO: Sorry, I thought you had.

13 Could you call it up on the screen.

14 MR. O'CONNOR: No objection.

15:17:39 15 THE COURT: You may display it as a demonstrative.

16 MR. CONDO: Thank you.

17 BY MR. CONDO:

18 Q Let's look at the first page of 7875.

19 Can you explain to the ladies and gentlemen of the
15:17:51 20 jury what they are seeing and what is shown on this first page
21 of this exhibit.

22 A So there are two filters shown in this exhibit. On the
23 right is the Recovery filter, which is the first generation of
24 the Recovery filter that was developed at NMT Medical. And on
15:18:11 25 the left is the G2 filter, which is the modification of the

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1 Recovery filter that was developed at Bard Peripheral
2 Vascular.

3 Q And was there an increase in the leg span between the
4 Recovery and the G2 filter?

5 A Yes, that's correct. So what you can see in the image,
6 the Recovery filter had a leg span of 32 millimeters and it
7 was increased to 40-millimeters, roughly 25 percent.

8 MR. CONDO: Can we go to the second page of the
9 exhibit, please.

10 BY MR. CONDO:

11 Q Would you explain to the ladies and gentlemen of the jury
12 what is depicted on this page of Exhibit 7875.

13 A So the modified G2 hooks were thicker than the original
14 Recovery hooks. So the Recovery were 8 and a half thousandths
15 of an inch diameter and the G2s were 10 and a half thousandths
16 of diameter. So about 24 percent thicker.

17 Q And where are the hooks located on the filter?

18 A So the hooks are located at the base of the filter.

19 MR. CONDO: Can we go back one page, please.

20 BY MR. CONDO:

21 Q Those are the little objects -- the little J-shaped hook
22 objects at the bottom of each filter; correct, sir?

23 A Yeah. So the filter mainly we can say consists of the
24 tip, then it's got legs that end with the hooks and then the
25 other upper structure is we call it arms, the ones that are

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15:19:48 1 bent.

2 MR. CONDO: Can we go to the third page of the
3 exhibit, please.

4 BY MR. CONDO:

15:19:58 5 Q What is shown on the third page of Exhibit 7875, sir?

6 A So it shows the modifications that were made to the
7 Recovery neck of the filter, which is right below the tip.
8 And it shows the Recovery filter had a relatively small radius
9 of curvature at the neck. And the G2 had a much bigger, much
10 better radius of curvature.

11 Q The Recovery had a sharper angle for the wires coming out
12 of the neck?

13 A Yes. I like to call it smaller radius of curvature, but
14 you can also describe it that way.

15:20:40 15 Q Now, was the change of the curvature of the arm wires
16 intended to improve fracture resistance of the filter in that
17 area?

18 A Yes, it was.

19 Q Is this change alone responsible for the overall improved
15:20:55 20 fracture resistance in the G2 filter?

21 A No, it is not.

22 Q Why not?

23 A Because there were other changes that also contributed to
24 fracture resistance. And so the lengthened arms, the wrists
15:21:11 25 at the end of the arms, and also the thicker hooks also had

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15:21:16 1 improved fracture resistance.

2 MR. CONDO: Let's turn, if we can, to the last page,
3 fourth page, of the exhibit.

4 BY MR. CONDO:

15:21:29 5 Q You said one of the items or design changes that
6 contributed to improved fracture resistance of the G2 was
7 longer arms?

8 A Yes, that's correct.

9 Q Explain to the ladies and gentlemen of the jury what
15:21:40 10 they're seeing on the fourth page of Exhibit 7875.

11 A On the right side it's shown Recovery filter with the arm
12 length below what we call the shoulder was 12-millimeters. In
13 the modified filter, the G2, that part was lengthened by
14 roughly about 50 percent, to about 17.5 millimeters.

15:22:07 15 Q I also think you said the addition of curved wrists to the
16 G2 filter contributed to the improved fracture resistance.
17 Where are the wrists shown or visible in this exhibit, sir?

18 A So they're shown at the very end of the arms on the G2.

19 Q Where the small arrow has been placed on the image?

15:22:35 20 A Yes, that's correct.

21 Q Now, did all of these changes, the longer arms, the
22 stronger hooks, the curved wrists, the change in the curvature
23 of the arms exiting the neck, did they all require a change in
24 the deployment system for the filter?

15:22:57 25 A Certainly at least some of them. So the new filter

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15:22:59 1 required a new delivery system. The old delivery system could
2 not be used to deliver it.

3 Q In your opinion, were all these changes from the Recovery
4 to the G2 intended to make the G2 a better filter?

15:23:13 5 A Yes. Absolutely.

6 Q Were you also involved in or did Bard also perform a
7 finite element analysis on the G2?

8 A Yes, we did.

9 Q And did you have a role in that?

15:23:27 10 A Yes, I did.

11 Q All right.

12 Let's talk a little bit about that if we can.

13 Ladies and gentlemen of the jury have heard the term
14 "finite element analysis" on multiple times. It's also
15:23:44 15 referred to as an FEA. Can you just help us recall what a
16 finite element analysis is?

17 A Sure. So finite element analysis is a computer simulation
18 and typically looks -- if you want to look at the filter, we
19 know the filter deformed during the either delivery or when it
15:24:08 20 is delivered to its intended location. And if we wanted to
21 estimate the stresses and the strains that are on the filter
22 because we can't observe it directly, then we use the computer
23 simulation to analyze it. So in the course of the simulation,
24 the filter would be deformed and then the software can
15:24:30 25 actually calculate stresses and strains in the filter due to

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15:24:33 1 these deformations.

2 MR. CONDO: Scott, would you call up Exhibit 5037,
3 please.

4 BY MR. CONDO:

15:24:45 5 Q Do you recognize Exhibit 5037, sir?

6 A Yes, I do.

7 Q And does your name appear as the originator on this
8 document?

9 A Yes, that's correct.

15:24:57 10 Q And what is the title of the document?

11 A Effects of Changes to the Recovery Filter and the Femoral
12 Delivery System on Filter Stresses Based on FEA Analysis.

13 Q And was this report prepared and is it maintained by Bard
14 in the regular course of business?

15:25:20 15 A Yes.

16 MR. CONDO: Your Honor, we offer Exhibit 5037.

17 MR. O'CONNOR: No objection.

18 MR. CONDO: May we publish?

19 THE COURT: Admitted.

15:25:32 20 Yeah, I admitted it.

21 (Exhibit 5037 admitted.)

22 MR. CONDO: I'm sorry. May we publish?

23 THE COURT: You may.

24 MR. CONDO: Let's see if we can turn to page 5,
15:25:46 25 section 10.

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15:25:48 1 BY MR. CONDO:

2 Q Can you tell the ladies and gentlemen of the jury the
3 conclusion from the FEA analysis that was done on the G2
4 filter?

15:25:59 5 A So just to give a little bit of background, in these
6 analysis the G2 filter was compared to the Recovery filter.
7 So it looked at the stresses in -- so for delivery the filter
8 needs to be compressed into small diameter.

9 So both the Recovery filter and G2 filter were
15:26:19 10 analyzed in the compressed state for delivery and also after
11 both filters were deployed in a simulated vena cava.

12 So the overall modified the filter design, which is
13 the G2, shows substantially lower peak stresses comparing to
14 the original design, up to 90 percent.

15:26:43 15 Q And was the objective of this study to evaluate the
16 potential changes to the Recovery filter and the delivery
17 system on the filter stresses, both loaded and unloaded?

18 A So it was both -- it was loaded and deployed.

19 Q And --

15:27:07 20 MR. CONDO: We can take that down.

21 BY MR. CONDO:

22 Q This was done on the Recovery filter; correct, sir?

23 A It was done actually both G2 and Recovery filter.

24 Q Okay.

15:27:16 25 Did Bard repeat on the G2 the respiratory testing,

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1 the EnduraTEC testing that was done on the Recovery filter?

2 A It did not do it directly.

3 Q Why not?

4 A Why the report didn't look at it?

5 Q What's that?

6 A Could you rephrase the question, please.

7 Q You said -- I asked you whether or not the EnduraTEC
8 testing was repeated on the G2, and you said not directly.

9 A The Endura testing, the test we went to first 36 and then
10 40 million cycles, that test on the Recovery filter was not
11 repeated on the G2 filter.

12 Q And why not?

13 A So there were a number of reasons. First of all we had --
14 we had data from three sources. First, we had the fatigue
15 test on the actual Recovery filter that we run to 400 million
16 cycles.

17 Secondly, the design changes that were made to the
18 filter were evaluated in the FEA analysis, the computer
19 simulation, and these changes, effectively the two biggest
20 changes which was the arm and the neck area and the thicker
21 hooks, they show a significant -- significantly lower stresses
22 for the G2 in both delivery system and deployed configuration.

23 And finally we did -- we ran a third test which was
24 actual physical fatigue test that looked at much greater
25 deformations. So the original Recovery filter, the filter was

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15:29:09 1 deformed for minimum of one millimeter and in this test the
2 filters were deformed roughly about ten millimeters and tests
3 was ran side by side, so both the Recovery filters and the G2
4 filters were tested side by side, and then the results show
15:29:28 5 that there was a significant improvement in the G2 filter as
6 far as the fatigue performance.

7 Q Now let me change to a different subject.

8 While you were at Bard, were you involved in
9 something called the G3?

15:29:45 10 A Yes, I was.

11 Q What was the G3 project?

12 A So after we developed the G2 filter, we had reports of
13 caudal migrations and we wanted to improve that aspect of the
14 filters, so the goal of the project was to design a new filter
15:30:12 15 that would be -- what have all of the positive aspects of G2
16 and also would have an improved caudal migration resistance.

17 Q And were you a member of the project team?

18 A Yes, I was.

19 Q And approximately when was the G3 project initiated?

15:30:31 20 A So my recollection is in 2006, I think about April.

21 Q Approximately how long did the G3 project last, if you
22 recall?

23 A So it lasted about a year and a half.

24 MR. CONDO: Can you call up Exhibit 8583, please.
25

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15:30:54 1 BY MR. CONDO:

2 Q Do you recognize the document on the screen as Exhibit
3 8583, sir?

4 A Yes.

15:31:03 5 Q And are you familiar with this document as a member of the
6 G3 project team?

7 A Yes, I am.

8 Q And does your name appear as a team member on this
9 document?

15:31:17 10 A Correct.

11 Q Was this document prepared in the regular and ordinary
12 course of business at Bard?

13 A Yes, it was.

14 MR. CONDO: And we would offer Exhibit 8583.

15:31:32 15 MR. O'CONNOR: No objection.

16 THE COURT: Admitted.

17 (Exhibit 8583 admitted.)

18 MR. CONDO: May we publish, Your Honor?

19 THE COURT: Yes.

15:31:45 20 BY MR. CONDO:

21 Q The date of this is April 19th, 2006. Can you tell the
22 ladies and gentlemen of the jury what this document is, sir.

23 A So Project Stress Report is typically a way to communicate
24 a project status to the upper management and it comes from the
15:32:08 25 team.

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15:32:11 1 Q And is this the first project status report or an early
2 project status report for the G3 project?

3 A Yes, that would be my understanding.

4 Q And does it involve team members from multiple disciplines
15:32:29 5 across the company line?

6 A Yes, that's correct.

7 Every project team, it doesn't actually matter
8 whether it's a vena cava filter or some other device, it
9 involves members from different departments of the company.

15:32:47 10 They're independent departments. Such as regulatory, we
11 always have an R&D person, quality, advanced manufacturing,
12 there's marketing, and oftentimes we also have a
13 representative from the manufacturing site.

14 Q Thank you.

15:33:02 15 MR. CONDO: You can take that down. And would you
16 present 8572, please.

17 BY MR. CONDO:

18 Q Mr. Chanduszek, do you recognize and can you identify
19 Exhibit 8572 on the screen before you?

15:33:18 20 A Yes, I can.

21 Q Is it a G3 caudal project meeting agenda from July 25,
22 2006?

23 A Yes, it is.

24 Q You are shown as a member of the G3 team?

15:33:36 25 A Yes, that's correct.

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15:33:37 1 Q Is it prepared in the regular and ordinary course of
2 business at Bard?

3 A Yes, it was.

4 MR. CONDO: Your Honor, we would offer Exhibit 8572.

15:33:50 5 MR. O'CONNOR: No objection.

6 THE COURT: Admitted.

7 (Exhibit 8572 admitted.)

8 MR. CONDO: May we publish?

9 THE COURT: You may.

15:33:57 10 BY MR. CONDO:

11 Q What does this document show, Mr. Chanduszko?

12 A So this document looks like it shows the -- it's an early
13 document, it seems, because it doesn't have any dates. And it
14 shows the topics, so it looks like it's a concept phase. And
15:34:23 15 it shows what kind of -- we're developing all kinds of

16 different testing, so it shows a list of these tests and shows
17 people who are responsible for the development of these tests.

18 Q Is this an early document on the G3 project that showed
19 what was likely to come as the project matured?

15:34:48 20 A At least for the concept phase, which is the first phase
21 of any new device development.

22 MR. CONDO: You can take that down. And would you
23 pull up 8573, please.

24 BY MR. CONDO:

15:35:05 25 Q Do you recognize Exhibit 8573, sir?

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15:35:09 1 A Yes, I do.

2 Q And is this another G3 caudal project meeting minutes?

3 A Yes, it is.

4 Q This is dated November 27, 2007?

15:35:24 5 A Correct.

6 Q And you're shown still as a member of the team on the

7 first page of the exhibit; correct?

8 A Yes.

9 Q And was this document prepared in the ordinary and regular

15:35:37 10 course of business at Bard?

11 A Yes, it was.

12 MR. CONDO: We would offer Exhibit 8573.

13 MR. O'CONNOR: No objection.

14 THE COURT: Admitted.

09:25:03 15 (Exhibit 8573 admitted.)

16 MR. CONDO: May we publish, Your Honor?

17 THE COURT: Yes.

18 BY MR. CONDO:

19 Q The date of this exhibit is some 18 months or so after the

15:36:06 20 April 2006 exhibit that we looked at.

21 MR. CONDO: I'd like to turn to page 4.

22 Actually, I'm -- yes, page 4.

23 Can you highlight all of those bullet points, please.

24 BY MR. CONDO:

15:36:33 25 Q At this point in time on the G3, what were the results of

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15:36:38 1 the tests that you were seeing for the product that was in the
2 concept phase?

3 A So the product went through some testing in the concept
4 phase and that effectively the last test that I recall that we
15:36:58 5 did was an animal study, and that is what the bullets talk
6 about.

7 So what they showed is that -- so we went through a
8 number of different variations of prototypes and we had to do
9 multiple testing. At the end we picked the prototype that
15:37:22 10 looked like it was performing the best. But we did have -- we
11 wanted to make sure it's going to work well, so these devices
12 were implanted in animals.

13 And what the data showed, that we did meet the
14 primary objective of the project, which was to improve caudal
15:37:45 15 migration of the filter. So the first bullet says the
16 migration results were excellent, the filters did not move.
17 But what it showed, we did have perforation results that were
18 concerning.

19 So we had three different prototypes we tested in
15:38:02 20 animals and one was unacceptable and the other two were
21 borderline acceptable.

22 So at this point the team decided to move back into
23 concept phase and redesign the filter to address perforation
24 concerns.

15:38:16 25 Q So at this point did the G3 filter concept essentially

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15:38:22 1 conclude?

2 A No, it did not.

3 Q What happened from this point forward?

4 A So from this point forward, there were other activities
15:38:35 5 and effectively we wanted to see if there's a way to improve
6 the perforation resistance or improve the perforation results
7 without negatively affecting other characteristics of the
8 filter.

9 Q Were the prototypes for the G3 ever commercialized?

15:38:57 10 A No, they were not.

11 Q You had to go to back and essentially start again?

12 A Yes. So effectively the conclusion made in the end was
13 that this particular idea that we started with, we can only
14 improve it up to a point. And we felt like we hit a dead end
15:39:18 15 and we had to go back and effectively bring some new ideas and
16 try to develop a brand new prototype that would look
17 differently and would work differently.

18 Q Let's talk, then, now about the Eclipse. After you moved
19 away from the G3, were you personally involved in other
15:39:39 20 projects to develop a filter to address caudal migration?

21 A Yes, I was.

22 Q Can you tell the ladies and gentlemen of the jury what
23 other projects you were involved with.

24 A So the main one I was involved with was the Denali filter.

15:40:00 25 Q And when was the Denali filter brought to market?

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15:40:04 1 A In about 2013.

2 Q And between 2006 as we've seen and 2013, did you continue
3 to work to develop filters that would improve complication
4 rates and performance?

15:40:16 5 A Yes, I did.

6 Q Okay. And did you continue to work to develop filters
7 that would improve efforts to reduce migration, both caudal
8 and cranial?

9 A Yes, that's correct.

15:40:31 10 Q Did you continue to work to develop products that would
11 improve the fracture resistance of IVC filters?

12 A Yes, that's correct.

13 Q How many years did it take between the inception of the
14 idea for the Denali filter and the date it was initially
15 commercialized?

16 A So the Denali was a natural extension of the G3. So after
17 the G3 when we hit the dead end effectively, we put the
18 project on hold and effectively work on other projects while
19 at the same time trying to develop a new filter platform,
20 which was eventually I think we had the idea roughly around
21 2008 or '9 where that idea that actually became a Denali
22 filter that was commercialized in 2013. So if we look at the
23 whole time, it was about seven years. If we exclude the pause
24 and the G3, it was at least four years, I would say.

15:41:42 25 Q And why did it take so long?

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15:41:46 1 A So, vena cava, we understand a lot of things about vena
2 cava, but at times vena cava can be a very dynamic and harsh
3 environment and it can be very unpredictable. So that is one
4 challenge.

15:42:05 5 The second challenge is that any filter, there are
6 many conflicting requirements that has to be balanced in the
7 design process. And in end, we have to absolutely meet every
8 single specification. And that is the difficulty.

9 Q Do some of the patents you hold for IVC filters actually
15:42:32 10 address elements of the Denali design?

11 A Yes, that is correct. There is actually a patent for the
12 Denali filter.

13 Q One last subject for you, sir. I want to talk about the
14 Eclipse filter.

15:42:45 15 What change was made from the G2X to the Eclipse
16 filter?

17 A So the G2X -- or Eclipse is electropolished G2X.

18 Q And can you describe what electropolishing is again for
19 the ladies and gentlemen of the jury.

15:43:05 20 A So one way to describe it is it's an electrochemical
21 process and it's effectively opposite to electroplating, which
22 most people are familiar with. So in electroplating a
23 material or metal can be deposited on the surface of the
24 metal. In this case, electropolishing is actually removing
15:43:32 25 material from the metal surface. So it removes little

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15:43:34 1 imperfections and you can make the filter wire much smoother.

2 Q Was it a simple process to learn how to electropolish the
3 G2 so that it could become the Eclipse?

4 A No, it was not.

15:43:48 5 Q Can you explain what the challenges were to the company in
6 trying to figure out how to electropolish the G2 -- G2X.

7 A So there's a number of challenges. First of all,
8 electropolishing is well-known and it's been used for a long
9 time when it comes to, for example, stainless steel. But
15:44:07 10 Nitinol was a relatively new material and not many people had
11 an expertise in electropolishing. Suddenly we didn't have an
12 expertise, so we had to go and look for outside people who are
13 experts in Nitinol. And there were some companies that could
14 do it.

15:44:29 15 And we wanted to take the G2X filter and
16 electropolish it as a whole. And these people work -- like I
17 said, they were experts in the fields, in the field, and it
18 took them many, many months to try to perfect the process.
19 And in the end they could not produce a usable filter. In
15:44:54 20 fact, these filters were much less fracture resistant than the
21 original G2X filter.

22 So when that happened, we had to abandon this
23 approach and we decided that we're going to try to
24 electropolish the components of the filter, which was less
15:45:15 25 ideal but definitely still acceptable. And in this way,

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1 finally these experts were able to electropolish the
2 components and then we were able to put the filter together
3 this way.

4 Q When you say electropolishing the components, what do you
5 mean?

6 A So effectively the filter wires. They had to take the
7 filter wires that are later assembled into the filter and
8 electropolish prior to assembly.

9 Q And did you believe that electropolishing the Eclipse
10 filter may improve the fracture resistance of the filter?

11 A Yes, that's my understanding.

12 Q Were the changes made to the Eclipse filter intended to
13 make an improvement compared to the G2X?

14 A Yes, absolutely.

15 Q And even though Bard developed later filters, including up
16 to and now the Denali, did you believe the G2X and Eclipse
17 filters were safe filters?

18 A Yes, they were.

19 MR. CONDO: I have no further questions.

20 THE COURT: Cross-examination.

C R O S S - E X A M I N A T I O N

22 BY MR. O'CONNOR:

23 Q Hi, Mr. Chanduszko. How are you today?

24 A Good. And you?

25 Q Let me just start with the last point you made. You were

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

1 talking to counsel for Bard about electropolishing. Do you
2 recall just now talking about that?

3 A Yes.

4 Q And you've talked about that in the past, haven't you?

5 Where you've been asked about electropolishing, whether it can
6 help with fracture resistance. And in other testimony you had
7 said "I'm afraid I can't answer it yes or no. I know it can
8 help and it can also hurt."

9 Do you remember testifying to that?

10 A Yes, as a general statement. Yes.

11 Q So in a previous time when you were placed under oath, you
12 testified that you just didn't know and told, under oath, that
13 electropolishing can help sometimes and can hurt sometimes;
14 correct?

15 A Yes. Before the process was developed, yes, that's
16 correct.

17 MR. O'CONNOR: Let's go to March 14, 2018, at page
18 206, please.

19 THE COURT: What exhibit number?

20 MR. O'CONNOR: Do we have an exhibit number?

21 MR. LOPEZ: 4540.

22 THE COURT: 454?

23 MR. STOLLER: 4540.

24 MR. O'CONNOR: 4540.

25

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15:48:06 1 BY MR. O'CONNOR:

2 Q Mr. Chanduszeko, this is testimony that you gave
3 previously, and I'm going to draw your attention to page 206
4 at line 11 through 14. And here was the question that you
15:48:29 5 were asked:

6 "Well, do you agree electropolishing can help with
7 fracture resistance; yes or no?

8 Your answer was: "I'm afraid I can't answer it yes
9 or no. I know it can help and I also know it can hurt."

15:48:42 10 Now, did I read that correctly, sir?

11 A Yes.

12 Q Thank you.

13 Now, sir, when you tested the Recovery, it was worse
14 than the Simon Nitinol filter in terms of tilting; correct?

15:49:13 15 A I -- I don't have a recollection that that was the case.

16 Q Do you recall it was worse than the Simon Nitinol in
17 tilting, perforation, and fracture? Do you recall that?

18 A I have to see the actual document to --

19 Q Let me ask you this --

15:49:28 20 A -- say.

21 Q -- you were there at the time the Recovery was launched;
22 correct? You were present at Bard when it was put into the
23 market?

24 A No, I was not.

15:49:37 25 Q You came after that, that's correct. You started at NMT.

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15:49:40 1 What year did you come to Bard, sir?

2 A In 2004.

3 Q And you do know that the Recovery was responsible for some
4 catastrophic events; correct?

15:49:56 5 A I'm not sure -- can you rephrase the question, please.

6 Q You became aware that the Recovery was in fact migrating
7 caudally; correct? Or, excuse me, in the cranial direction.
8 Upward.

9 A Yes. There were some incidents like that, that's correct.

15:50:12 10 Q And you knew that the Recovery was causing serious
11 injuries and catastrophic events to patients; true?

12 A There were some cases that there was some association, but
13 I can't -- I don't know if I can say it that the Recovery
14 filter was actually causing the effects.

15:50:34 15 Q But you started developing the G2 because of issues with
16 the Recovery; right?

17 A So yes. The goal was to improve migration resistance was
18 one of the goals.

19 Q Migration resistance you were trying to improve was
15:50:52 20 migration that went up, cephalad. Or cranial, excuse me.

21 A That is correct.

22 Q You did not test the G2 for caudal or downward migration;
23 correct?

24 A We did.

15:51:03 25 Q Pardon me?

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15:51:04 1 A We did test for caudal migration, yes.

2 Q You tested after the G2 was out on the market; right?

3 A That's not correct.

4 Q You did not do a fatigue resistance test for the G2, did

15:51:23 5 you?

6 A We did comparative test that I described earlier against

7 the Recovery filter.

8 Q Let me ask you this.

9 MR. O'CONNOR: Let's look at Exhibit 1295.

15:51:40 10 BY MR. O'CONNOR:

11 Q You know who Micky Graves is; correct?

12 A Yes.

13 Q And earlier you talked about the saluting arm test; right?

14 A Yes, I suppose. Saluting arm fatigue testing, yes.

15:52:01 15 MR. O'CONNOR: May I publish 1295, Your Honor?

16 THE COURT: You may.

17 BY MR. O'CONNOR:

18 Q The subject of this e-mail from Micky Graves to Charlie

19 Simpson is "Historical FEA Analysis."

15:52:19 20 Did I read that correctly?

21 A Yes, that's correct.

22 MR. O'CONNOR: Felice, let's go down below to the

23 start of the e-mail.

24 BY MR. O'CONNOR:

15:52:34 25 Q Charlie Simpson had asked you a question: "Andrzej,

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15:52:37 1 thanks. Do we have the same analysis for the G2?"

2 Do you see that?

3 A Yes, I do.

4 Q And then let's go to -- Mr. Graves responded to it;
15:52:46 5 correct?

6 This is a response from Micky Graves, do you see
7 that?

8 A Yes, that's what it looks like.

9 Q And he says, "No. But we intend to get a similar study
15:52:58 10 completed. The team agrees."

11 Now, did I read that correctly?

12 A Yes.

13 Q And Micky Graves -- who was an engineer at Bard; correct?

14 A Yes. He was the engineer in Bard, that's correct.

15:53:14 15 Q And he goes on to say, "I have talked with Andrzej as to
16 why we did not do this for the G2 in the beginning."

17 Did I read that correct?

18 A Yes, that's correct.

19 Q And he says, "The reason was that the G2 longer arms with
15:53:30 20 the wrists would not engage the cava wall and would not have
21 a -- and would not have saluting arms."

22 Did I read that correctly?

23 A Yes.

24 Q He goes on to say, "Therefore, the engineering staff did
15:53:42 25 not see the need to run an FEA for a saluting arm failure mode

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15:53:46 1 that was not realistic. They felt the data would still fall
2 out of the acceptable range of the Goodman fatigue
3 evaluation."

4 Did I read that correctly?

15:53:56 5 A Yes, that is correct.

6 Q And then Mr. Graves went on to say this:

7 "I am not satisfied with that answer at all. Just
8 because we didn't like the answer, we didn't think the answer
9 would support our design change as a viable option, we chose
10 not to run the test. We settled on the arm bend fatigue
11 tester to give us an answer that we are now 12 times more
12 fracture resistant under specific loading questions.

13 "The bigger question still is, 'Is 12 times more
14 resistant enough?' Now, we are stuck answering the same
15 question a year later in order to consider the trimming of the
16 wrist option."

17 Did I read that correctly, sir?

18 A Yes, that's correct.

19 Q And the G2 was on the market at this time; true?

15:54:47 20 A That's correct. He's talking about --

21 Q Excuse me, sir. The G2 was on the market at the time of
22 this e-mail; correct?

23 A Yes.

24 Q And you knew the G2 was experiencing caudal migration
15:54:57 25 almost immediately after it was on the market; correct?

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15:55:02 1 A So within -- I don't know exactly but, yes, we were aware
2 the G2 filter had some caudal migrations.

3 MR. O'CONNOR: Excuse me one moment.

4 May I publish to the jury, Your Honor?

15:55:58 5 THE COURT: Publish what?

6 MR. O'CONNOR: I'm sorry. Exhibit 1221. I believe
7 it's in evidence.

8 THE COURT: It is. You may publish.

9 BY MR. O'CONNOR:

15:56:13 10 Q Mr. Chanduszko, do you see here a Health Hazard Evaluation
11 dated February 15, 2006?

12 A Yes, I do.

13 Q That was just before the e-mail by Mr. Graves; correct?

14 A Sir, I don't recall the exact month but yes. Probably
15 yes.

16 Q I thought the e-mail was about March 21, 2006. Do you
17 recall that?

18 A So yes.

19 Q And this health hazard evaluation came about February 15,
15:56:42 20 2006, do you see that?

21 A Correct.

22 Q It says, "Bard has received ten reports of migration --
23 one cephalad, nine caudal -- of the G2 IVC filter as of
24 February 9, 2006."

15:56:54 25 Did I read that correctly?

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15:56:56 1 A Yes. If you can make it a little bigger, it would help,
2 please.

3 Q Pardon me? Oh.

4 MR. O'CONNOR: Felice, can you enlarge that for
15:57:05 5 Mr. Chanduszeko.

6 THE WITNESS: Thank you.

7 BY MR. O'CONNOR:

8 Q Let me read that again. "Bard has received ten reports of
9 migration -- one cephalad, nine caudal -- of the G2 filter as
15:57:19 10 of February 9, 2006."

11 Now, did I read that correctly?

12 A Yes.

13 Q Thank you. And you also know, Mr. Chanduszeko, that there
14 were reports to Bard about the G2 fracturing; correct?

15:57:36 15 A At what point of time?

16 Q Pardon me?

17 A What point of time? Just general --

18 Q After the launch you were aware of that.

19 A Yes.

15:57:43 20 Q You were aware there were fracture -- G2 fracture
21 investigations going on at Bard; correct?

22 A I'm not sure if there was an investigation.

23 MR. O'CONNOR: Natalie Wong fracture report.

24 That's okay. Let's put that one up.
25

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

15:58:33 1 BY MR. O'CONNOR:

2 Q Mr. Chanduszek --

3 MR. O'CONNOR: Your Honor, this is Exhibit 1222. May
4 we publish to the jury?

15:58:40 5 THE COURT: You may.

6 MR. O'CONNOR: Felice, can we go to page 6.

7 BY MR. O'CONNOR:

8 Q Mr. Chanduszek, this is a slide presentation that you were
9 involved in preparing; correct?

15:59:02 10 A I'm not sure if that's the case.

11 Q All right. We were told by Mr. Randall you may have been
12 involved in this.

13 A So that looks to me like a slide that was prepared by
14 Dr. Kaufman.

15:59:16 15 Q Well, in any event, you were aware of the EVEREST study;
16 correct?

17 A Yes. Absolutely.

18 Q And the EVEREST study was a study that lasted a specific
19 period of time to study retrievability of the G2; correct?

15:59:31 20 A Correct.

21 Q And within that specific period of time, 180 days or
22 however long it was, the G2 was found to have filter failures;
23 correct?

24 A I'm not sure what it means, filter failures. Do you mean
15:59:46 25 complaints?

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

15:59:48 1 Q Well, here, let me just break it down for you.

2 This is what's called a Venn diagram?

3 A Yes, this is a Venn diagram. Yes.

4 Q And you can see where in the different circles there are
16:00:02 5 G2 complications including penetration, tilt, and caudal
6 migration. Do you see that?

7 A Yes, I do.

8 Q Do you see in the intersecting circles is where more than
9 one and even two or three complications occurred to a single
16:00:16 10 filter; true?

11 A Correct.

12 Q And this all occurred within the period of the EVEREST
13 study; right?

14 A That would be my best guess.

16:00:24 15 Q And let's go to page 9.

16 And this was another slide that was prepared about
17 filter complications found in MAUDE data. You know what MAUDE
18 data is; true?

19 A Yes, I do.

16:00:44 20 Q And here you can see again this is the G2 and these are
21 filter complications of the G2 that Bard learned about and as
22 of January 7, 2008. Do you see that?

23 A Yes, I do.

24 Q And here, separate and apart from EVEREST, Bard was
16:01:03 25 learning that the G2 filter was penetrating, tilting, and

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

16:01:07 1 caudally migrating. Do you see that?

2 A Yes, I do.

3 Q And in the intersecting circles you can see there were
4 patients who had more than one filter complication. Do you
16:01:17 5 see that?

6 A Yes, I do.

7 MR. O'CONNOR: And then go to page 13, Felice.

8 BY MR. O'CONNOR:

9 Q And this statement from Bard states the following,
16:01:33 10 Mr. Chanduszko:

11 "Caudal migration, tilt, perforation, and fractures
12 are the most commonly occurring complications associated with
13 the filter. Eliminating these failure modes would reduce
14 number of filter complaints from 152 to 34, by 78 percent."

16:01:50 15 Do you see that?

16 A Yes, I see that.

17 Q And setting aside the testing that was done by you and the
18 engineers, the G2 filter went on and Bard began to receive
19 reports about complications that included migration, tilting,
16:02:09 20 perforation, and fracture; true?

21 A Yes, that's correct.

22 MR. O'CONNOR: Let's go to 5324.

23 BY MR. O'CONNOR:

24 Q Now, sir, this is entitled an R&D Technical Report.

16:02:36 25 MR. O'CONNOR: May I publish this, Your Honor?

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

16:02:37 1 THE COURT: You may.

2 BY MR. O'CONNOR:

3 Q Do you see that?

4 A Yes, I do.

16:02:45 5 Q And you prepared similar reports for Bard; correct?

6 A Correct.

7 Q That's where you will actually publish test results that

8 were repeatable and show them in a report, and then you will

9 file the report so engineers could go back and see what was

16:03:05 10 done and validate it by testing; right?

11 A So the report would show the -- would be a record of test

12 results or summary thereof.

13 Q Okay. Now, earlier you talked to Mr. Condo about the

14 400 million cycles that you tested; correct?

16:03:34 15 A Correct.

16 Q Sir, you told us the only place that is noted is in a lab

17 notebook; right?

18 A That would be my recollection.

19 Q You're not aware of any technical report or final report

16:03:49 20 that contains that finding; true?

21 A So the there's two parts of it.

22 Q Sir, are you aware of any technical report that contains

23 those findings? Are you aware -- you didn't bring anything

24 other than this lab notebook; true?

16:04:02 25 A There is a report that should show some of these results,

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

16:04:07 1 the 36 million cycles.

2 Q 36 million. But the only place the 4 million --
3 400 million cycles is referenced are in notes in this lab
4 notebook; correct?

16:04:18 5 A I can't tell that that's the case. I suspect that's the
6 case. It was --

7 Q Thank you.

8 A -- 20 years ago.

9 MR. O'CONNOR: Let's go to 5037.

16:05:06 10 May I publish to the jury, Your Honor?

11 THE COURT: You may.

12 BY MR. O'CONNOR:

13 Q Mr. Chanduszek, you talked to Mr. Condo about this
14 document earlier; correct?

16:05:16 15 A That's correct.

16 Q And as I understand it, this was a test of the filter in
17 the delivery system; true?

18 A That was part of it.

19 Q The test of the strains that are put on the filter when
16:05:29 20 it's put in the tube that's going to be placed in a patient;
21 right?

22 A That was part of the simulation, yes.

23 Q And this test assumed there was no tilt; right?

24 A When the filter is loaded into the delivery system there
16:05:43 25 cannot be any tilt.

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

16:05:46 1 Q So tilt was not measured in this test; right?

2 A In the delivery system there can be no tilt.

3 Q Fine. And your test assumed there was no perforation --
4 no perforation; correct?

16:05:59 5 A That's correct.

6 Q The test assumed that the filter was perfectly centered.
7 True?

8 A Yes. As comparison to another filter, that's correct.

9 Q And, sir, when you test do you agree that you should be
16:06:26 10 testing for worst case conditions?

11 A As a general statement, yes.

12 Q And do you agree that a medical device company like Bard
13 must know the environment of use where it is going -- where it
14 intends to place a medical device such as a filter?

16:06:45 15 A Yes, they should understand it as much as possible.

16 Q And you agree and have just seen evidence here today that
17 after the Recovery was launched, it failed with different
18 filter complications; correct?

19 A I don't know if it failed. It had different
16:07:04 20 complications, which is exactly true for any filter.

21 Q The Recovery had filter complications and the intent of
22 the G2 was to improve upon those complications; correct?

23 A That is correct.

24 Q And you saw documentation here today where, when the G2
16:07:19 25 was launched, it experienced complications as well. We just

CROSS-EXAMINATION - ANDRZEJ CHANDUSZKO

16:07:24 1 looked at those in the EVEREST; correct?

2 A That is correct.

3 Q And you know the Eclipse experienced fractures as well,
4 true?

16:07:31 5 A It's true. It's true for any filter, in fact.

6 Q It's true for the G2, it's true for the Eclipse, and it's
7 true for the Recovery; correct?

8 A Correct. Any filter on the market whether it's Bard or
9 not Bard it's true.

16:07:43 10 MR. O'CONNOR: Move to strike as nonresponsive.

11 THE COURT: Overruled.

12 BY MR. O'CONNOR:

13 Q What we're here talking about and what we looked at today
14 was evidence about the Bard filter failures; correct?

16:07:51 15 A That is correct.

16 Q And what we looked at were documents where Bard
17 acknowledged filter failures and the need to get -- to
18 eliminate those failures; right?

19 A I'm sorry, could you repeat, please.

16:08:05 20 Q Sure. The EVEREST PowerPoint. We looked at that and saw
21 Bard's knowledge that it needed to eliminate those failures in
22 the filters; true?

23 A Well, we definitely wanted to eliminate these, yes.

24 MR. O'CONNOR: Thank you. That's all I have.

16:08:20 25 THE COURT: Redirect.

REDIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

16:08:23 1 MR. CONDO: Yes, Your Honor.

2 May we publish Exhibit 1295?

3 THE COURT: You may.

4 MR. CONDO: And would you highlight the very last
16:08:49 5 sentence in the second paragraph, please.

6 R E D I R E C T E X A M I N A T I O N

7 BY MR. CONDO:

8 Q Mr. Chanduszeko, I want to give you an opportunity to
9 explain an answer that you didn't have a chance to explain on
16:09:03 10 cross-examination.

11 What is the reference in Mr. Graves' e-mail to
12 trimming the wrist?

13 A So he was considering a modification to the G2 filter and
14 the modification would involve trimming the wrist of the
16:09:23 15 filter. So that was after the filter was already on the
16 market and we were looking into, effectively, G3.

17 Q So he was looking ahead and looking for a test that might
18 validate a future design?

19 A That is correct.

16:09:40 20 MR. CONDO: If we could call up Exhibit 1222, please.

21 BY MR. CONDO:

22 Q Do you see on the first page of Exhibit 1222 the reference
23 to a new filter platform being called the G2 Platinum?

24 A Yes, I see that.

16:10:01 25 Q That was the effort to terminally electropolish the

REDIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

16:10:06 1 filter; correct?

2 A That is correct.

3 Q That's the project that failed, never got off the ground,
4 because the experts couldn't figure out how to do it?

16:10:17 5 MR. O'CONNOR: Objection. Leading.

6 THE COURT: Sustained.

7 BY MR. CONDO:

8 Q Why did that project never get off the ground, sir?

9 A Because in the process of trying to figure out how to
16:10:27 10 electropolish the whole filter, despite their best efforts and
11 despite their expertise, they were not able to make a filter
12 that would be -- that would have an acceptable fatigue
13 resistance. It was actually worse than the G2X.

14 MR. CONDO: May I display Exhibit 1222, Your Honor?

16:10:55 15 THE COURT: You may.

16 BY MR. CONDO:

17 Q Now, I want to continue with our discussion about
18 electropolishing.

19 Does electropolishing remove material?

16:11:07 20 A Yes, it does.

21 Q So if electropolishing is not done right, can it diminish
22 the fracture resistance of a metal?

23 A If it's not done right, then it would -- it could make it
24 worse.

16:11:27 25 Q And is that why, when you answered Mr. O'Connor's question

REDIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

16:11:35 1 yes and no about electropolishing, is that what you referring
2 to, that sometimes it can be better, sometimes it can be
3 worse?

4 A Yeah. Effectively, without knowing what the process is,
16:11:47 5 what kind of results it produces, then it is difficult to tell
6 up front whether the process will actually help or hurt.

7 You need to complete the process and make sure you
8 know that what's coming out is good. Only then you can tell
9 yes, it is good. But sometimes, as I mention, the platinum
16:12:08 10 actually, despite best efforts, they could not produce a good
11 filter. So because of that it can actually hurt.

12 MR. CONDO: No further questions.

13 THE COURT: You can step down, Mr. Chanduszko. You
14 can step down. Thank you.

16:12:44 15 MS. HELM: Your Honor, at this time we call Dr. John
16 DeFord by videotape.

17 May I read the summary, Your Honor?

18 THE COURT: You may.

19 MS. HELM: Dr. John DeFord is a senior vice president
16:12:59 20 for science, technology, and clinical affairs at Bard. In
21 this role Dr. DeFord is responsible for research and
22 development functions at the various divisions at Bard.

23 Dr. DeFord obtained both machelors -- mach- -- I'll
24 get it out -- bachelors and masters degrees in engineering
16:13:20 25 before obtaining his Ph.D in electrical biomedical engineering

REDIRECT EXAMINATION - ANDRZEJ CHANDUSZKO

16:13:25 1 in 1990.

2 Prior to joining Bard in 2004, Dr. DeFord held
3 various positions at other medical device manufacturers,
4 including serving as the president and chief officer of Cook
16:13:38 5 Medical, Inc.

6 There are no exhibits with Dr. DeFord's deposition.

7 THE COURT: All right.

8 (Video testimony of Dr. DeFord was played.)

9 THE COURT: Let's stop the video there.

16:29:29 10 All right, ladies and gentlemen, we'll plan to start
11 again tomorrow morning at 9 o'clock. We'll excuse you. Thank
12 you.

13 (The jury exited the courtroom at 4:29.)

14 THE COURT: Counsel, I have a 4:30 hearing. I'll
16:30:03 15 calculate the time while you're collecting stuff and give it
16 to you before you leave.

17 MS. HELM: Do you want the time for the deposition,
18 Your Honor?

19 THE COURT: I thought I would wait until the end and
16:30:15 20 then allocate it. So this will all be allocated to
21 defendants, but we'll make an adjustment in the morning.

22 MS. HELM: Thank you, Your Honor.

23 THE COURT: Counsel, as of today plaintiffs have used
24 31 hours and 1 minute; Defendants 21 hours and 2 minutes. And
16:32:44 25 that's without any allocation of time to plaintiffs for

DeFord.

I also want to note on the record that we had a sidebar this morning and I mentioned my memory of a previous 403 ruling I had done on cephalad migration deaths. That order I had in mind was the order at Docket 11041.

We'll plan to see you at 8:30 tomorrow morning. Please remember tomorrow at the end of the day, 4:30, we're talking about jury instructions.

MR. ROGERS: Thank you, Your Honor.

(End of p.m. session transcript.)

* * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 2nd day of October, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter